

FOI 26-2354 scope as at 4 December 2025:

'Please provide a document detailing the cancellation, suspension and/or removal of each spinal cord stimulator device from the Australian Register of Therapeutic Goods (ARTG), including the reason(s) for each action and the current decision status.'

The Category 2 request relates to:

1. Sponsors (exhaustive list): Medtronic Australasia Pty Ltd

2. GMDN Text provided in the attached excel spreadsheet

Clarification received on 31 October 2025 (applicants' response in blue):

Could you please confirm that:

1. this request relates only to products sponsored by Medtronic – we confirm that this request only relates to products sponsored by Medtronic Australasia Pty Ltd.
2. the GMDN codes listed in 2a-c. We confirm that, as with FOI 26-2352, the request does not only relate to those limited GMDN terms – they are simply provided by way of example, noting our comment that this is not an exhaustive list of GMDN terms. The request relates to all GMDNs applicable to spinal cord stimulator devices per our answer below.

Further, could you please confirm that the GMDN codes specifically relate to spinal cord stimulator devices only (rather than all GMDN terms). The request does not only relate to the implantable spinal cord stimulator devices – it also relates to lead kits, generators, remote controls, holders and other products the TGA considers to be necessary for spinal cord stimulator treatment.

In addition, grateful for your confirmation that this request is limited to a list of ARTG entries cancelled or suspended from 01/07/2012 to 27/10/2025, with the reason for removal of the entry. Yes. For the avoidance of doubt, the request is limited to the sponsor named in the FOI Application, Medtronic Australasia Pty Ltd. Also, for the avoidance of doubt, by "a list of ARTG entries" we understand this would include the following information: ARTG IDs, Product Name, date of removal of the entry and the reason for removal of the entry, for each spinal cord stimulator device.

Notes:

Only 4 (Medtronic) ARTGs were cancelled by the TGA - highlighted in green. All other ARTG entries were cancelled at the request of the Sponsor for their own reasons (these are not provided to the TGA).

Class AIMD were reclassified to Class III in 2021

St Jude Medical Australia (nil entries - Abbott purchased St Jude in 2017)

Note: The scope clairification on 18 Nov 25 stated "As discussed, it has come to our attention that some of the ARTG IDs referenced in the document released under FOI 1097-1819 in June 2019 do not produce any search results when searching these ARTG IDs on the cancellations and suspensions register". I have double checked and the listed ARTGs are included in the provided list where they meet the FOI search criteria. ie, those not in the list were cancelled prior to 30 June 2012, or had a different sponsor.

Note: The search occasionally produced multiple entries for an ARTG; you will see that a manufacturer or product changed between these entries.

GMDN Code Name

36007 Stimulator, electrical, analgesic, spinal cord [36007]
36534 Power supply, battery pack [36534]
44040 Neural-tissue electrical stimulation lead [44040]
44045 Electrode/lead, stimulator, implantable, neurological
44900 Pacemaker/defibrillator port safety plug [44900]
45252 Active-implantable-device communicator [45252]
47809 Percutaneous electrical stimulation lead external pulse generator cable, reusable
48054 Neural-tissue electrical stimulation lead adaptor
57996 Implantable stimulator control magnet [57996]
60363 Implantable electrical stimulation device management software
61472 Trial spinal cord/peripheral nerve percutaneous analgesic electrical stimulation system pulse generator
61588 Implantable spinal cord electrical stimulation system programmer
62422 Implantable lumbar neuromuscular electrical stimulation system pulse generator [62422]
62423 Spinal cord/peripheral nerve implantable analgesic electrical stimulation system lead, wired connection
62424 Spinal cord/peripheral nerve implantable analgesic electrical stimulation system control unit
62425 Spinal cord/peripheral nerve implantable analgesic electrical stimulation system programmer
64578 Central nervous system electrical stimulation system lead stylet
64970 Spinal cord/peripheral nerve implantable analgesic electrical stimulation system pulse generator, implantable
65159 Electrical-only medical device connection adaptor, single-use
65308 Spinal cord/peripheral nerve implantable analgesic electrical stimulation system lead extension
65530 Spinal cord/peripheral nerve implantable analgesic electrical stimulation system external electrode
65531 Spinal cord/peripheral nerve implantable analgesic electrical stimulation system lead, wireless connection
65532 Spinal cord/peripheral nerve implantable analgesic electrical stimulation system pulse generator, extracorporeal
65533 Trial spinal cord/peripheral nerve percutaneous analgesic electrical stimulation system lead
66826 Spinal cord rehabilitation transcutaneous electrical stimulation system
67082 Spinal cord/peripheral nerve electrical stimulation pulse generator implantation tool
67084 Implantable electrical stimulation lead epidural tunneller
67179 Implantable electrical stimulation lead anchor
67213 Percutaneous electrical stimulation lead external pulse generator cable, single-use
67518 Implantable pulse generator external transceiver
67573 Spinal cord implantable electrical stimulation lead dimensional trial

FOI 26-2352 scope as at 4 December 2025:

'Category 1: Updated Adverse Event Reporting for spinal cord stimulator devices (SCS Devices) Please provide a document equivalent to the document released under FOI 1097-1819, containing adverse event information reported via the DAEN for selected GMDN Names and Codes as set out in the attached excel spreadsheet, for the period from 25 January 2019 to the date of processing this request

Category 2: Please provide a document detailing the cancellation, suspension and/or removal of each SCS Device from the Australian Register of Therapeutic Goods (ARTG), including the reason(s) for each action and the current decision status.

The Category 2 request relates to:

1. Sponsors (exhaustive list):

- a. St Jude Medical Australia Pty Ltd; and
- b. Abbott Medical Australia Pty Ltd.

2. GMDN Text provided in the attached excel spreadsheet

Clarification received on 31 October 2025 (applicants' response in blue):

Could you please confirm:

1. that this request relates only to products sponsored by 1(a) and (b); **We confirm that the Category 1 request does not only relate to the products sponsored by the companies listed at 1(a) and 1(b) of the FOI Application. For the avoidance of doubt, Category 1 relates to all sponsors of spinal cord stimulator devices which are the subject of the FOI document released under FOI 1097-1819. The Category 2 request relates only to products sponsored by the companies listed at 1(a) and 1(b) of the FOI Application.**

2. with the GMDN codes listed in 2a-c – the Category 2 request does not only relate to those limited GMDN terms – they are simply provided by way of example, noting our comment that this is not an exhaustive list of GMDN terms. The Category 2 request relates to all GMDNs applicable to spinal cord stimulator devices per our answer below.

Further, could you please confirm that the GMDN codes specifically relate to spinal cord stimulator devices only (rather than all GMDN terms). **The Category 2 request does not only relate to the implantable spinal cord stimulator devices – it also relates to lead kits, generators, remote controls, holders and other products the TGA considers to be necessary for spinal cord stimulator treatment.**

In addition, grateful for your confirmation that:

1. this request is limited to a list of adverse event reports, and the information within those reports, that were received by the TGA from 01/07/2012 to 27/10/2025 – **The Category 1 request is for new adverse event reporting information from 25 January 2019 to the date of processing the request, as we understand the document released under FOI 1097-1819 covers adverse event reports received by the TGA from 1 July 2012 to 24 January 2019. However, please let us know if our understanding is incorrect. For the avoidance of doubt, the Category 1 request is not limited to the sponsors in Category 2, 1(a) and 1(b) of the FOI Application. For the avoidance of doubt, we confirm that Category 1 relates to all sponsors of spinal cord stimulator devices which are the subject of the FOI document released under FOI 1097-1819.**

2. and a list of ARTG entries cancelled or suspended from 01/07/2012 to 27/10/2025, with the reason for removal of the entry. **Yes. For the avoidance of doubt, the Category 2 request is limited to the sponsors in Category 2, 1(a) and 1(b) of the FOI Application. Also, for the avoidance of doubt, by "a list of ARTG entries" we understand this would include the following information: ARTG IDs, Product Name, date of removal of the entry and the reason for removal of the entry, for each spinal cord stimulator device.**

Notes:

Only 4 (Medtronic) ARTGs were cancelled by the TGA - highlighted in green. All other ARTG entries were cancelled at the request of the Sponsor for their own reasons (these are not provided to the TGA).

Class AIMD were reclassified to Class III in 2021

St Jude Medical Australia (nil entries - Abbott purchased St Jude in 2017)

Note: The scope cliaification on 18 Nov 25 stated "As discussed, it has come to our attention that some of the ARTG IDs referenced in the document released under FOI 1097-1819 in June 2019 do not produce any search results when searching these ARTG IDs on the cancellations and suspensions register". I have double checked and the listed ARTGs are included in the provided list where they meet the FOI search criteria. ie, those not in the list were cancelled prior to 30 June 2012, or had a different sponsor.

Note: The search occassionally produced multiple entries for an ARTG; you will see that a manufacturer or product changed between these entries.

GMDN Code Name

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47809 Percutaneous electrical stimulation lead external pulse generator cable, reusable
48054 Neural-tissue electrical stimulation lead adaptor
57996 Implantable stimulator control magnet [57996]
60363 Implantable electrical stimulation device management software
61472 Trial spinal cord/peripheral nerve percutaneous analgesic electrical stimulation system pulse generator
61588 Implantable spinal cord electrical stimulation system programmer
62422 Implantable lumbar neuromuscular electrical stimulation system pulse generator [62422]
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67082 Spinal cord/peripheral nerve electrical stimulation pulse generator implantation tool
67084 Implantable electrical stimulation lead epidural tunneller
67179 Implantable electrical stimulation lead anchor
67213 Percutaneous electrical stimulation lead external pulse generator cable, single-use
67518 Implantable pulse generator external transceiver
67573 Spinal cord implantable electrical stimulation lead dimensional trial

FOI 26-2355 scope as at 4 December 2025:

'Please provide a document detailing the cancellation, suspension and/or removal of each spinal cord stimulator device from the Australian Register of Therapeutic Goods (ARTG), including the reason(s) for each action and the current decision status.'

This request relates to:

1. Sponsor (exhaustive list): Boston Scientific Pty Ltd

2. GMDN Text provided in the attached excel spreadsheet

Clarification received on 31 October 2025 (applicants' response in blue):

Could you please confirm that:

1. this request relates only to products sponsored by Boston Scientific Pty Ltd. Yes.
2. the GMDN codes listed in 2a-c. We confirm, as with FOI 26-2354 and FOI 26-2352, the request does not only relate to those limited GMDN terms – they are simply provided by way of example, noting our comment that this is not an exhaustive list of GMDN terms. The request relates to all GMDNs applicable to spinal cord stimulator devices per our answer below.

Further, could you please confirm that the GMDN codes specifically relate to spinal cord stimulator devices only (rather than all GMDN terms). The request does not only relate to the implantable spinal cord stimulator devices – it also relates to lead kits, generators, remote controls, holders and other products the TGA considers to be necessary for spinal cord stimulator treatment.

In addition, grateful for your confirmation that this request is limited to a list of ARTG entries cancelled or suspended from 01/07/2012 to 27/10/2025, with the reason for removal of the entry. Yes. For the avoidance of doubt, the request is limited to the sponsor named in the FOI Application, Boston Scientific Pty Ltd. Also, for the avoidance of doubt, by "a list of ARTG entries" we understand this would include the following information: ARTG IDs, Product Name, date of removal of the entry and the reason for removal of the entry, for each spinal cord stimulator device.

Notes:

Only 4 (Medtronic) ARTGs were cancelled by the TGA - highlighted in green. All other ARTG entries were cancelled at the request of the Sponsor for their own reasons (these are not provided to the TGA).

Class AIMD were reclassified to Class III in 2021

St Jude Medical Australia (nil entries - Abbott purchased St Jude in 2017)

Note: The scope clairification on 18 Nov 25 stated "As discussed, it has come to our attention that some of the ARTG IDs referenced in the document released under FOI 1097-1819 in June 2019 do not produce any search results when searching these ARTG IDs on the cancellations and suspensions register". I have double checked and the listed ARTGs are included in the provided list where they meet the FOI search criteria. ie, those not in the list were cancelled prior to 30 June 2012, or had a different sponsor.

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67518 Implantable pulse generator external transceiver
67573 Spinal cord implantable electrical stimulation lead dimensional trial

ART ID	ARTC Status	Start Date	Cancelled Date	ARTC Item-Reason Relation	ARTC Name	Class	Spender	Spender Name	Product ID	Product Status	Product Name	Intended Purpose	Functional Description	DAIS Code	DAIS Code	Manufacturer ID	Manufacturer	Manufacturer Active Flag	Manufacturer Name ARTG Entries
139001	Revised	7/30/2008	8/08/2011	Cancelled by Sponsor	Boston Scientific	PM/AND	23030	Boston Scientific	PI	21255000	Cancelled	Precision - Stimulator, electrical, anergic, spine	The Precision Imp 3600			18222	Stimulator, electric	Y	Boston Scientific, N
162422	Revised	11/9/2009	2/4/2015	Cancelled by Sponsor	Boston Scientific	PI/Class II	23032	Boston Scientific	PI	26336000	Cancelled	Precision Connector For M1 - Electrode, stimulat	the Precision The M1 Connector			18222	Neural-tissue stimul	Y	Boston Scientific, N
107910	Revised	2/5/2012	4/4/2015	Cancelled by Sponsor	Boston Scientific	PI/Class II	23031	Boston Scientific	PI	35387000	Cancelled	Infinium 16 Lead & Splitter 16 Pin	Infinium 16 Lea 16 Pin			18222	Neural-tissue stimul	Y	Boston Scientific, N
107911	Revised	2/5/2012	4/4/2015	Cancelled by Sponsor	Boston Scientific	PI/Class II	23032	Boston Scientific	PI	35388000	Cancelled	Infinium 16 Lead & Splitter 16 Pin	Infinium 16 Lea 16 Pin			18222	Neural-tissue stimul	Y	Boston Scientific, N
107912	Revised	2/5/2012	3/14/2014	Cancelled by Sponsor	Boston Scientific	PI/Class II	23033	Boston Scientific	PI	35389000	Cancelled	Infinium 16 Lead & Splitter 16 Pin	Infinium 16 Lea 16 Pin			18222	Neural-tissue stimul	Y	Boston Scientific, N
205793	Revised	8/2/2013	1/6/2013	Cancelled by Sponsor	Boston Scientific	PI/AND	23031	Boston Scientific	PI	37154000	Cancelled	Precision Spectra Implantable Pulse Generator	Precision Spec. Imp. 3600			18222	Stimulator, electric	Y	Boston Scientific, N
205794	Revised	8/2/2013	1/6/2013	Cancelled by Sponsor	Boston Scientific	PI/AND	23032	Boston Scientific	PI	37155000	Cancelled	Precision Spectra Implantable Pulse Generator	Precision Spec. Imp. 3600			18222	Stimulator, electric	Y	Boston Scientific, N
206304	Revised	2/1/2013	2/4/2015	Cancelled by Sponsor	Boston Scientific	PI/Class II	23032	Boston Scientific	PI	37643000	Cancelled	Precision Spectra External Trial Stimulator	CS-5132 The Stimulator The Trial Stimulator			18222	Stimulator, electric	Y	Boston Scientific, N
219581	Revised	3/3/2014	3/0/2013	Cancelled by Sponsor	Boston Scientific	PI/Class II	23032	Boston Scientific	PI	410835	Cancelled	Magnet Model 4520 - Implantable	stimulator the Magnet is the Magnet The uses it			55491	Implantable stimul	N	Cameron Health, N
211187	Revised	3/30/2012	3/0/2013	Cancelled by Sponsor	Boston Scientific	PI/Class II	23032	Boston Scientific	PI	44283000	Cancelled	Precision Implantable Pulse Generator SC-1112 - Sti	The Precision Imp 3600			18222	Stimulator, electric	Y	Boston Scientific, N
211188	Revised	3/30/2012	3/0/2013	Cancelled by Sponsor	Boston Scientific	PI/Class II	23032	Boston Scientific	PI	44284000	Cancelled	Precision Implantable Pulse Generator SC-1112 - Sti	The Precision Imp 3600			18222	Stimulator, electric	Y	Boston Scientific, N
211189	Revised	3/30/2012	3/0/2013	Cancelled by Sponsor	Boston Scientific	PI/Class II	23032	Boston Scientific	PI	44285000	Cancelled	Precision Implantable Pulse Generator SC-1112 - Sti	The Precision Imp 3600			18222	Stimulator, electric	Y	Boston Scientific, N
211190	Revised	3/1/2014	2/4/2015	Cancelled by Sponsor	Boston Scientific	PI/Class II	23032	Boston Scientific	PI	44901000	Cancelled	Precision External Trial Stimulator SC-5112	Stimulate The SC-5112 The external tria			18222	Stimulator, electric	Y	Boston Scientific, N
211191	Revised	3/1/2014	2/4/2015	Cancelled by Sponsor	Boston Scientific	PI/Class II	23032	Boston Scientific	PI	44902000	Cancelled	Precision External Trial Stimulator SC-5112	Stimulate The SC-5112 The external tria			18222	Stimulator, electric	Y	Boston Scientific, N
211192	Revised	3/1/2014	2/4/2015	Cancelled by Sponsor	Boston Scientific	PI/Class II	23032	Boston Scientific	PI	44903000	Cancelled	Precision External Trial Stimulator SC-5112	Stimulate The SC-5112 The external tria			18222	Stimulator, electric	Y	Boston Scientific, N
217543	Revised	11/5/2016	3/0/2016	Cancelled by Sponsor	Boston Scientific	PI/Class II	23032	Boston Scientific	PI	54305000	Cancelled	Infinium CS Trial Lead - Stimulator, electric, an	Infinium CS Trial Lead - Stimulator, electric, an			18222	Stimulator, electric	Y	Boston Scientific, N
283602	Revised	16/4/2012	16/4/2012	Cancelled by Sponsor	Boston Scientific	PI/AND	23032	Boston Scientific	PI	56600000	Cancelled	Precision Non-Implantable Pulse Generator Mod The Precision Now	The system is exten			18222	Stimulator, electric	Y	Boston Scientific, N
283603	Revised	16/4/2012	16/4/2012	Cancelled by Sponsor	Boston Scientific	PI/AND	23032	Boston Scientific	PI	56601000	Cancelled	Precision Non-Implantable Pulse Generator Mod The Precision Now	The system is exten			18222	Stimulator, electric	Y	Boston Scientific, N
283604	Revised	16/4/2012	28/4/2013	Cancelled by Sponsor	Boston Scientific	PI/AND	23032	Boston Scientific	PI	56600000	Cancelled	Precision Non-Implantable Pulse Generator & Free The Precision Now	The system is exten			18222	Stimulator, electric	Y	Boston Scientific, N
283605	Revised	16/4/2012	28/4/2013	Cancelled by Sponsor	Boston Scientific	PI/AND	23032	Boston Scientific	PI	56601000	Cancelled	Precision Non-Implantable Pulse Generator & Free The Precision Now	The system is exten			18222	Stimulator, electric	Y	Boston Scientific, N
286709	Revised	14/4/2017	16/4/2013	Cancelled by Sponsor	Boston Scientific	PI/AND	23032	Boston Scientific	PI	57453000	Cancelled	Precision Montage M16 Contact Implantable Pu	The Boston Scien			18222	Stimulator, electric	Y	Boston Scientific, N
318260	Revised	3/6/2016	16/4/2013	Cancelled by Sponsor	Boston Scientific	PI/AND	23032	Boston Scientific	PI	64540200	Cancelled	Spectra Wave Implantable Pulse Generator	The Spectra Wave The Spectra Wave			18222	Stimulator, electric	Y	Boston Scientific, N
330320	Revised	2/2/2013	2/2/2013	Cancelled by Sponsor	Boston Scientific	PI/AND	23032	Boston Scientific	PI	70805000	Cancelled	WaveWriter Alpha Prime 1200	Wavewriter Alpha 1200			18222	Stimulator, electric	Y	Boston Scientific, N
362970	Revised	2/2/2013	16/4/2013	Cancelled by Sponsor	Boston Scientific	PI/AND	23032	Boston Scientific	PI	70805000	Cancelled	WaveWriter Alpha Prime 1200	Wavewriter Alpha 1200			18222	Stimulator, electric	Y	Boston Scientific, N
362971	Revised	2/2/2013	16/4/2013	Cancelled by Sponsor	Boston Scientific	PI/AND	23032	Boston Scientific	PI	70806000	Cancelled	WaveWriter Alpha Prime 1200	Wavewriter Alpha 1200			18222	Stimulator, electric	Y	Boston Scientific, N
362972	Revised	2/2/2013	16/4/2013	Cancelled by Sponsor	Boston Scientific	PI/AND	23032	Boston Scientific	PI	70806000	Cancelled	WaveWriter Alpha Prime 1200	Wavewriter Alpha 1200			18222	Stimulator, electric	Y	Boston Scientific, N
362973	Revised	2/2/2013	16/4/2013	Cancelled by Sponsor	Boston Scientific	PI/AND	23032	Boston Scientific	PI	70808000	Cancelled	WaveWriter Alpha Prime 1200	Wavewriter Alpha 1200			18222	Stimulator, electric	Y	Boston Scientific, N
402020	Revised	28/1/2012	16/4/2013	Cancelled by Sponsor	Boston Scientific	PI/Class II	23032	Boston Scientific	PI	88482000	Cancelled	Spectra Wave Implantable Pulse Generator	The Spectra Wave The Spectra Wave			18222	Stimulator, electric	Y	Boston Scientific, N
402021	Revised	28/1/2012	26/4/2014	Cancelled by Sponsor	Boston Scientific	PI/Class II	23032	Boston Scientific	PI	88488000	Cancelled	Spectra Wave Implantable Pulse Generator	The Spectra Wave The Spectra Wave			18222	Stimulator, electric	Y	Boston Scientific, N
												Montage M16 Contact Implantable Pu	The Boston Scien			18222	Montage M16 Contact Implantable Pu		
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All ARTGs were cancelled under Section 41GL(d) of the Act, sponsor-initiated cancellations. There's only 8 out of the 30 that are not on the website (the others are all there). I suspect this is because they were cancelled back in 2010, 2013, and 2016 and there may not have been processes in place to publish on the website at that point in time.

ARTG Number	Type of Action	Action Date
106668	Cancelled by sponsor - Section 41GL(d)	30/06/2010
121880	Cancelled by sponsor - Section 41GL(d)	30/06/2010
125910	Cancelled by sponsor - Section 41GL(d)	28/06/2013
126002	Cancelled by Sponsor - Section 41GL(d) (published on the website)	30/10/2024
126003	Cancelled by Sponsor - Section 41GL(d)	28/06/2013
126004	Cancelled by Sponsor - Section 41GL(d) (published on the website)	30/10/2024
127126	Cancelled by Sponsor - Section 41GL(d)	21/06/2016
129091	Cancelled by Sponsor - Section 41GL(d) (published on the website)	30/06/2021
131047	Cancelled by Sponsor - Section 41GL(d) (published on the website)	28/06/2024
131836	Cancelled by Sponsor - Section 41GL(d)	30/06/2010
131944	Cancelled by Sponsor - Section 41GL(d) (published on the website)	30/10/2024
131946	Cancelled by sponsor - Section 41GL(d)	28/06/2013
131947	Cancelled by Sponsor - Section 41GL(d) (published on the website)	18/05/2017
132097	Cancelled by Sponsor - Section 41GL(d) (published on the website)	30/10/2024
154866	Cancelled by Sponsor - Section 41GL(d) (published on the website)	25/07/2018

154912	Cancelled by sponsor - Section 41GL(d)	21/06/2016
155013	Cancelled by Sponsor - Section 41GL(d) (published on the website)	30/10/2024
158502	Cancelled by Sponsor - Section 41GL(d) (published on the website)	16/02/2017
160826	Cancelled by Sponsor - Section 41GL(d) (published on the website)	30/06/2025
177594	Cancelled by Sponsor - Section 41GL(d) (published on the website)	30/11/2021
202323	Cancelled by Sponsor - Section 41GL(d) (published on the website)	07/04/2022
205793	Cancelled by Sponsor - Section 41GL(d) (published on the website)	16/06/2023
215750	Cancelled by Sponsor - Section 41GL(d) (published on the website)	22/06/2022
279911	Cancelled by Sponsor - Section 41GL(d) (published on the website)	07/06/2024
279913	Cancelled by Sponsor - Section 41GL(d) (published on the website)	05/11/2024
283692	Cancelled by Sponsor - Section 41GL(d) (published on the website)	16/06/2023
286709	Cancelled by Sponsor - Section 41GL(d) (published on the website)	16/06/2023
287158	Cancelled by Sponsor - Section 41GL(d) (published on the website)	22/11/2019
289235	Cancelled by Sponsor - Section 41GL(d) (published on the website)	07/06/2024
289236	Cancelled by Sponsor - Section 41GL(d) (published on the website)	12/05/2022

DIR Number	ARTG ID	Date of report	Device Class	GMDN Text	Sponsor Name	Manufacturer Name	Clinical Event	Problem Type Level 1
126826	336330	03/12/2025	AIMD	Analgesic spinal cord electrical stimulation system pulse generator implantable	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	Unresolved pain in implant site to lower limb. Revision procedure performed and device was repositioned.	Adverse Event Without Identified Device or Use Problem
126509	336330	27/11/2025	AIMD	Analgesic spinal cord electrical stimulation system pulse generator implantable	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	Pain at implant site.	Adverse Event Without Identified Device or Use Problem
126277	336330	26/11/2025	AIMD	Analgesic spinal cord electrical stimulation system pulse generator implantable	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	Inadequate pain relief.	Output Problem
126510	396984	26/11/2025	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Abbott Medical Australia Pty Ltd	Abbott Medical	Unable to tighten screw to point of locking.	Mechanical Problem
126508	400392	26/11/2025	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Pain at the implantable pulse generator pocket site, superficial and loose in pocket. Revision procedure to reposition IPG.	Patient Device Interaction Problem
126266	336330	24/11/2025	AIMD	Analgesic spinal cord electrical stimulation system pulse generator implantable	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	swelling	Patient Device Interaction Problem
125713	336573	18/11/2025	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	Inadequate pain relief.	Patient Device Interaction Problem
124767	396985	26/11/2025	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Abbott Medical Australia Pty Ltd	Abbott Medical	Pain at IPG site and communication issues.	Communication or Transmission Problem
124370	336330	05/11/2025	AIMD	Analgesic spinal cord electrical stimulation system pulse generator implantable	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	Device explant due to inadequate pain relief.	Patient Device Interaction Problem
123843	336330	25/10/2025	AIMD	Analgesic spinal cord electrical stimulation system pulse generator implantable	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	uncomfortable stimulation.	Patient Device Interaction Problem
123845	336330	25/10/2025	AIMD	Analgesic spinal cord electrical stimulation system pulse generator implantable	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	Undesirable increase in stimulation.	Electrical /Electronic Property Problem
123941	396985	06/11/2025	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Pain at implantation requiring revision.	Patient Device Interaction Problem
123944	336573	25/10/2025	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	headache	Patient Device Interaction Problem
123566	374776	21/10/2025	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	ineffective therapy	Electrical /Electronic Property Problem
123186	397013	02/12/2025	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Abbott Medical Australia Pty Ltd	Abbott Medical	Device near to breaking skin	Patient Device Interaction Problem
122871	336573	01/11/2025	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	impedance, stimulation issue	Electrical /Electronic Property Problem
122736	377339	25/10/2025	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	lead migrated	Patient Device Interaction Problem
122603	374776	08/10/2025	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Uncomfortable stimulation, vomiting, heat at pocket site. impedance.	Electrical /Electronic Property Problem
122603	374776	08/10/2025	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Uncomfortable stimulation, vomiting, heat at pocket site. impedance.	Temperature Problem
122160	336330	03/10/2025	AIMD	Analgesic spinal cord electrical stimulation system pulse generator implantable	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	difficulty establishing connection	Connection Problem
122160	336330	03/10/2025	AIMD	Analgesic spinal cord electrical stimulation system pulse generator implantable	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	difficulty establishing connection	Electrical /Electronic Property Problem
122059	490125	01/10/2025	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Ineffective stimulation due to high impedance.	Electrical /Electronic Property Problem
121761	336330	30/09/2025	AIMD	Analgesic spinal cord electrical stimulation system pulse generator implantable	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	Pain and inadequate stimulation relief.	Electrical /Electronic Property Problem
121563	336330	25/09/2025	AIMD	Analgesic spinal cord electrical stimulation system pulse generator implantable	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	Revision due to incompatibility.	Patient Device Interaction Problem
121368	336573	24/09/2025	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	Inadequate pain relief.	Electrical /Electronic Property Problem
121368	336573	24/09/2025	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	Inadequate pain relief.	Patient Device Interaction Problem
121266	400373	22/09/2025	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Infection, swelling and soreness.	Patient Device Interaction Problem
121257	400373	19/09/2025	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Multiple complications post implant of the device.	Patient Device Interaction Problem
120921	336330	17/09/2025	AIMD	Analgesic spinal cord electrical stimulation system pulse generator implantable	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	Inadequate pain relief.	Patient Device Interaction Problem
120783	374776	22/10/2025	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Leads eroded through the skin, causing skin infection.	Adverse Event Without Identified Device or Use Problem
119640	397013	25/09/2025	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Abbott Medical Australia Pty Ltd	Abbott Medical	Unable to charge device.	Communication or Transmission Problem
119358	374776	23/10/2025	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Redness, pus, itchiness and infection at implant site.	Patient Device Interaction Problem
119343	327091	15/11/2025	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Mainstay Medical Australia Pty Ltd	Mainstay Medical Limited	Lead strain relief loop pulled out.	Mechanical Problem
119239	396984	29/10/2025	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Abbott Medical Australia Pty Ltd	Abbott Medical	Device explanted.	Insufficient Information
119277	396987	25/09/2025	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Abbott Medical Australia Pty Ltd	Abbott Medical	Pain and discomfort at implantation site.	Patient Device Interaction Problem
119237	374776	29/10/2025	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Lead migration	Patient Device Interaction Problem
119240	374776	29/10/2025	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Lead migration.	Mechanical Problem
119053	336573	22/08/2025	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	Difficult positioning.	Activation, Positioning or Separation Problem
118963	396985	29/10/2025	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Abbott Medical Australia Pty Ltd	Abbott Medical	Inadequate pain relief. Difficulty removing leads during revision procedure.	Communication or Transmission Problem
118882	336573	21/08/2025	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	Inadequate pain relief. Difficulty removing leads during revision procedure.	Connection Problem
118882	336573	21/08/2025	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	Inadequate pain relief. Difficulty removing leads during revision procedure.	Patient Device Interaction Problem
118933	336573	20/08/2025	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	Discharge from incision. Wound debridement was completed.	Adverse Event Without Identified Device or Use Problem
118727	336573	16/08/2025	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	Shoulder pain due to infection.	Patient Device Interaction Problem
118489	336330	13/08/2025	AIMD	Analgesic spinal cord electrical stimulation system pulse generator implantable	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	Patient experienced pain.	Patient Device Interaction Problem
118055	336330	12/08/2025	AIMD	Analgesic spinal cord electrical stimulation system pulse generator implantable	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	Explant	Adverse Event Without Identified Device or Use Problem
118415	400373	11/08/2025	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Small bowel obstruction	Patient Device Interaction Problem
118205	400392	27/10/2025	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	dehiscence	Patient Device Interaction Problem
118096	400392	03/12/2025	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Infection at implantable pulse generator site.	Adverse Event Without Identified Device or Use Problem
116949	336330	31/07/2025	AIMD	Analgesic spinal cord electrical stimulation system pulse generator implantable	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	Pain	Patient Device Interaction Problem
117246	440130	23/10/2025	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Abbott Medical Australia Pty Ltd	Abbott Medical	Infection at the IPG site.	Appropriate Term/Code Not Available
116953	440130	18/10/2025	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Abbott Medical Australia Pty Ltd	Abbott Medical	Infection at IPG site.	Adverse Event Without Identified Device or Use Problem
116955	377340	25/07/2025	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	High impedance.	Electrical /Electronic Property Problem
116809	336573	24/07/2025	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	Patient removed the implanted trial leads	Use of Device Problem
116609	400392	13/10/2025	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Patient developed an infection.	Patient Device Interaction Problem
116593	374776	15/11/2025	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Infection, seroma and a fluid ball near the lead site.	Patient Device Interaction Problem
116279	336330	19/07/2025	AIMD	Analgesic spinal cord electrical stimulation system pulse generator implantable	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	Implantation site pain and charging difficulty.	Electrical /Electronic Property Problem
116143	336573	18/07/2025	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	Infection	Adverse Event Without Identified Device or Use Problem
115980	374776	16/07/2025	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	High impedance on one lead.	Electrical /Electronic Property Problem
115871	336573	16/07/2025	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	Change in stimulation location.	Electrical /Electronic Property Problem
115872	377340	15/07/2025	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Dural tear.	Appropriate Term/Code Not Available
115776	400392	02/10/2025	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Infection, redness and soreness implant site.	Patient Device Interaction Problem
115803	400392	02/10/2025	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Trailer fell of site and revision procedure was performed.	Mechanical Problem
115765	374776	19/07/2025	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	High impedance	Electrical /Electronic Property Problem
114898	336330	16/08/2025	AIMD	Analgesic spinal cord electrical stimulation system pulse generator implantable	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	Infection	Patient Device Interaction Problem

115622	400290	15/10/2025	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Inadequate stimulation.	Electrical /Electronic Property Problem
115514	374776	18/07/2025	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	migration	Mechanical Problem
115382	400392	09/07/2025	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	High impedance and difficulty connecting charger to implantable pulse generator.	Electrical /Electronic Property Problem
115304	400392	06/10/2025	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Infection, swelling, redness	Patient Device Interaction Problem
115141	400392	23/09/2025	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Inadequate pain relief.	Patient Device Interaction Problem
114705	400392	01/07/2025	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Repositioned	Adverse Event Without Identified Device or Use Problem
114517	397013	02/08/2025	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Abbott Medical Australia Pty Ltd	Abbott Medical	Device unable to be charged or communicate with external devices.	Electrical /Electronic Property Problem
114519	374776	12/07/2025	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Ineffective therapy	Output Problem
114519	374776	12/07/2025	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Ineffective therapy	Patient Device Interaction Problem
114402	377339	22/08/2025	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Ineffective therapy	Output Problem
114263	327091	16/10/2025	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Mainstay Medical Australia Pty Ltd	Mainstay Medical Limited	Unable to run therapy. Out-of-range/high-impedance failures.	Electrical /Electronic Property Problem
114263	327091	16/10/2025	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Mainstay Medical Australia Pty Ltd	Mainstay Medical Limited	Unable to run therapy. Out-of-range/high-impedance failures.	Output Problem
114262	396987	25/07/2025	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Abbott Medical Australia Pty Ltd	Abbott Medical	Discomfort	Patient Device Interaction Problem
114134	374776	29/07/2025	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Ineffective therapy	Appropriate Term/Code Not Available
114134	374776	29/07/2025	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Ineffective therapy	Electrical /Electronic Property Problem
114134	374776	29/07/2025	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Ineffective therapy	Output Problem
113911	396984	29/08/2025	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Abbott Medical Australia Pty Ltd	Abbott Medical	ocket pain	Patient Device Interaction Problem
113912	396985	29/08/2025	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Abbott Medical Australia Pty Ltd	Abbott Medical	It was reported that the patient's IPG stopped connecting to external devices following an unrelated procedure.	Connection Problem
113910	374776	23/06/2025	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Lost therapy due to lead fracture	Material Integrity Problem
113910	374776	23/06/2025	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Lost therapy due to lead fracture	Output Problem
113784	400290	08/09/2025	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Explant surgery due to inadequate pain relief.	Appropriate Term/Code Not Available
113758	374776	20/06/2025	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Ineffective therapy and pain experienced at the IPG site.	Electrical /Electronic Property Problem
113691	400392	17/09/2025	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Pain and inadequate therapy.	Electrical /Electronic Property Problem
113632	327091	26/08/2025	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Mainstay Medical Australia Pty Ltd	Mainstay Medical Limited	impedance	Electrical /Electronic Property Problem
113492	374776	29/08/2025	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Abbott Medical Australia Pty Ltd	Abbott Medical	Ineffective therapy and high impedance.	Electrical /Electronic Property Problem
113373	400392	17/06/2025	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Explantation due to pain at the implant site.	Patient Device Interaction Problem
113382	400392	28/09/2025	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Revision surgery due to communication problems between remote control and implantable pulse generator.	Communication or Transmission Problem
113347	374776	17/06/2025	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	High impedance resulting in auto reducing therapy strength.	Electrical /Electronic Property Problem
113303	374776	14/06/2025	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	High impedances of the lead.	Electrical /Electronic Property Problem
112739	336330	02/08/2025	AIMD	Analgesic spinal cord electrical stimulation system pulse generator implantable	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	Explanted due to pain	Adverse Event Without Identified Device or Use Problem
112913	396985	11/06/2025	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Abbott Medical Australia Pty Ltd	Abbott Medical	IPG failed to establish communication with external device	Electrical /Electronic Property Problem
112917	396985	11/06/2025	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Abbott Medical Australia Pty Ltd	Abbott Medical	Explant	Adverse Event Without Identified Device or Use Problem
112885	392267	19/09/2025	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Medtronic Australasia Pty Ltd	Medtronic Inc	Unable to connect device and charge.	Electrical /Electronic Property Problem
112738	400392	07/06/2025	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Bluetooth fault code, charger interference and device reset.	Electrical /Electronic Property Problem
112738	400392	07/06/2025	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Bluetooth fault code, charger interference and device reset.	Protective Measures Problem
112649	396985	26/09/2025	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Abbott Medical Australia Pty Ltd	Abbott Medical	Erythema at the IPG site.	Patient Device Interaction Problem
112481	400373	04/06/2025	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Remote control was unable to communicate with IPG	Appropriate Term/Code Not Available
112481	400373	04/06/2025	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Remote control was unable to communicate with IPG	Communication or Transmission Problem
112486	400291	28/08/2025	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Increased charging.	Electrical /Electronic Property Problem
112332	336573	04/06/2025	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	Change in stimulation	Output Problem
112332	336573	04/06/2025	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	Change in stimulation	Patient Device Interaction Problem
112352	396985	10/08/2025	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Abbott Medical Australia Pty Ltd	Abbott Medical	pain at IPG site	Adverse Event Without Identified Device or Use Problem
112257	374776	29/07/2025	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Patients leads migrated and patient experienced ineffective therapy.	Patient Device Interaction Problem
112190	374776	30/05/2025	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Ineffective therapy.	Electrical /Electronic Property Problem
112048	374776	19/07/2025	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Ineffective therapy due to migration lead.	Adverse Event Without Identified Device or Use Problem
111896	400290	14/08/2025	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Lack of pain relief.	Adverse Event Without Identified Device or Use Problem
111797	374776	04/09/2025	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	impedance, ineffective therapy	Electrical /Electronic Property Problem
111798	377339	12/07/2025	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Ineffective therapy and pain	Output Problem
111793	400373	11/08/2025	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	EOL indicator	Protective Measures Problem
111407	336573	16/08/2025	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	Impaired healing, infection	Adverse Event Without Identified Device or Use Problem
111385	214839	11/08/2025	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Medtronic Australasia Pty Ltd	Medtronic Inc	Patient experienced pain.	Patient Device Interaction Problem
111383	389797	11/08/2025	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Medtronic Australasia Pty Ltd	Medtronic Inc	Premature battery depletion and shocking sensation at the site.	Electrical /Electronic Property Problem
111301	374776	21/06/2025	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Ineffective therapy, high impedance	Electrical /Electronic Property Problem
111168	400392	09/05/2025	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Pocket pain	Patient Device Interaction Problem
111088	397013	22/08/2025	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Abbott Medical Australia Pty Ltd	Abbott Medical	communication issue	Communication or Transmission Problem
111098	374776	08/05/2025	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	High impedance	Electrical /Electronic Property Problem
111100	374776	08/05/2025	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Inability to enter device into MRI mode due to high impedance	Appropriate Term/Code Not Available
111100	374776	08/05/2025	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Inability to enter device into MRI mode due to high impedance	Electrical /Electronic Property Problem
111055	400392	07/05/2025	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	The patient experienced prolonged charging time and increased pain at the implantable pulse generator (IPG) site when charging for more than 30 minutes.	Patient Device Interaction Problem
110945	440130	22/08/2025	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Abbott Medical Australia Pty Ltd	Abbott Medical	Pain and infection and implant site.	Adverse Event Without Identified Device or Use Problem

110944	377339	03/05/2025	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Ineffective therapy	Output Problem
110913	400291	02/05/2025	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Pain and discomfort	Patient Device Interaction Problem
110776	385873	05/06/2025	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	High and low impedances on patient's leads after quad bike accident.	Electrical /Electronic Property Problem
110709	396984	26/04/2025	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Abbott Medical Australia Pty Ltd	Abbott Medical	Adverse Event Without Identified Device or Use Problem	Pain at pocket site
110710	396984	26/04/2025	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Abbott Medical Australia Pty Ltd	Abbott Medical	Adverse Event Without Identified Device or Use Problem	Pain at insertion site
110555	440130	22/08/2025	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Abbott Medical Australia Pty Ltd	Abbott Medical	Reduced wound healing and infection following IPG implant, resulting in device explant.	Patient Device Interaction Problem
110546	377339	29/05/2025	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Ineffective therapy	Electrical /Electronic Property Problem
110508	384012	19/08/2025	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	abscess	Patient Device Interaction Problem
110509	384012	02/05/2025	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Ineffective therapy	Electrical /Electronic Property Problem
110509	384012	02/05/2025	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Ineffective therapy	Output Problem
110492	400392	10/07/2025	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Inadequate pain relief from Spinal Cord Stimulator (SCS)	Patient Device Interaction Problem
110442	400392	18/04/2025	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Lack of therapeutic effect	Adverse Event Without Identified Device or Use Problem
110446	400392	08/07/2025	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Device migration resulted in extended charging, heat and burning sensation.	Electrical /Electronic Property Problem
110446	400392	08/07/2025	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Device migration resulted in extended charging, heat and burning sensation.	Patient Device Interaction Problem
110439	384012	18/04/2025	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Ineffective therapy	Output Problem
110378	396984	08/05/2025	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Abbott Medical Australia Pty Ltd	Abbott Medical	connection issues	Connection Problem
110260	374776	19/07/2025	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Skin erosion	Output Problem
110260	374776	19/07/2025	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Skin erosion	Patient Device Interaction Problem
110257	336573	15/04/2025	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	Inadequate pain relief	Patient Device Interaction Problem
110129	336330	25/07/2025	AIMD	Analgesic spinal cord electrical stimulation system pulse generator implantable	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	Inadequate pain relief	Output Problem
110202	396985	12/04/2025	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Abbott Medical Australia Pty Ltd	Abbott Medical	Device placed into surgery mode and unable to communicate with external devices.	Communication or Transmission Problem
110142	400392	31/07/2025	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Unable to connect and communicate the remote control with the device	Communication or Transmission Problem
110132	327091	11/04/2025	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Mainstay Medical Australia Pty Ltd	Mainstay Medical Limited	Therapeutic output failure	Electrical /Electronic Property Problem
110132	327091	11/04/2025	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Mainstay Medical Australia Pty Ltd	Mainstay Medical Limited	Therapeutic output failure	Material Integrity Problem
110132	327091	11/04/2025	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Mainstay Medical Australia Pty Ltd	Mainstay Medical Limited	Therapeutic output failure	Output Problem
110089	336330	27/05/2025	AIMD	Analgesic spinal cord electrical stimulation system pulse generator implantable	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	Inadequate pain relief.	Electrical /Electronic Property Problem
110017	374776	21/06/2025	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Ineffective therapy	Electrical /Electronic Property Problem
109940	400392	07/04/2025	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	discomfort, migration of device	Patient Device Interaction Problem
109942	400392	07/04/2025	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Pocket pain	Patient Device Interaction Problem
109950	400290	07/04/2025	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Difficulty charging implantable pulse generator (IPG).	Electrical /Electronic Property Problem
109766	396984	08/05/2025	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Abbott Medical Australia Pty Ltd	Abbott Medical	unable to communicate between devices	Communication or Transmission Problem
109788	400290	23/06/2025	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Inadequate stimulation.	Electrical /Electronic Property Problem
109691	400392	18/06/2025	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Pain at IPG pocket site, resulting in system explantation.	Adverse Event Without Identified Device or Use Problem
109356	336330	27/03/2025	AIMD	Analgesic spinal cord electrical stimulation system pulse generator implantable	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	Explant	Adverse Event Without Identified Device or Use Problem
109548	440130	27/03/2025	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Abbott Medical Australia Pty Ltd	Abbott Medical	discomfort at implant site	Adverse Event Without Identified Device or Use Problem
109549	440130	24/04/2025	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Abbott Medical Australia Pty Ltd	Abbott Medical	Infection	Adverse Event Without Identified Device or Use Problem
109297	327091	10/09/2025	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Mainstay Medical Australia Pty Ltd	Mainstay Medical Limited	impedance, revision surgery	Electrical /Electronic Property Problem
109275	400392	20/03/2025	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Loss of stimulation.	Electrical /Electronic Property Problem
109011	336330	18/03/2025	AIMD	Analgesic spinal cord electrical stimulation system pulse generator implantable	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	revision due to pain	Patient Device Interaction Problem
109152	336573	18/03/2025	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	Inadequate stimulation	Output Problem
109152	336573	18/03/2025	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	Inadequate stimulation	Patient Device Interaction Problem
109125	400291	04/06/2025	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Infection at site resulting in device explantation	Patient Device Interaction Problem
109127	400392	04/06/2025	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Pain at implantable pulse generator (IPG) site.	Patient Device Interaction Problem
109139	327091	15/07/2025	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Mainstay Medical Australia Pty Ltd	Mainstay Medical Limited	High impedance	Electrical /Electronic Property Problem
109093	400392	02/06/2025	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	It was reported that the patient experienced intermittent pain and burning sensation near the Spinal Cord Stimulation (SCS) Implantable Pulse Generator (IPG) site requiring explantation	Patient Device Interaction Problem
108922	374776	02/05/2025	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Ineffective therapy	Electrical /Electronic Property Problem
108922	374776	02/05/2025	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Ineffective therapy	Output Problem
108922	374776	02/05/2025	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Ineffective therapy	Patient Device Interaction Problem
108940	374776	21/06/2025	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Ineffective therapy, high impedance	Electrical /Electronic Property Problem
108906	400290	28/05/2025	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Inadequate stimulation.	Patient Device Interaction Problem
108792	336330	07/03/2025	AIMD	Analgesic spinal cord electrical stimulation system pulse generator implantable	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	Explanted	Adverse Event Without Identified Device or Use Problem
108556	374776	03/07/2025	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Abbott Medical Australia Pty Ltd	Abbott Medical	CSF leak and headache	Mechanical Problem
108324	400291	12/05/2025	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Revision due to pain.	Appropriate Term/Code Not Available
108186	214839	05/06/2025	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Medtronic Australasia Pty Ltd	Medtronic Inc	High impedance.	Electrical /Electronic Property Problem
108162	374776	20/02/2025	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Cerebrospinal fluid leakage during a permanent spinal cord stimulator implant.	Appropriate Term/Code Not Available
108157	336573	20/02/2025	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	Inadequate pain relief.	Patient Device Interaction Problem
108150	336330	19/02/2025	AIMD	Analgesic spinal cord electrical stimulation system pulse generator implantable	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	Device explanted due to inadequate pain relief.	Patient Device Interaction Problem
107997	384012	14/02/2025	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Ineffective therapy	Output Problem
107491	336330	27/02/2025	AIMD	Analgesic spinal cord electrical stimulation system pulse generator implantable	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	Pain at the Closed Loop Stimulator implant site.	Adverse Event Without Identified Device or Use Problem
107307	374776	25/01/2025	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Ineffective therapy	Output Problem

107227	374776	25/01/2025	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Lead migration and compete loss of coverage.	Patient Device Interaction Problem
106510	400392	27/03/2025	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	explantation due to infection, pain	Adverse Event Without Identified Device or Use Problem
106342	336330	08/01/2025	AIMD	Analgesic spinal cord electrical stimulation system pulse generator implantable	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	Pain.	Patient Device Interaction Problem
106362	336330	07/01/2025	AIMD	Analgesic spinal cord electrical stimulation system pulse generator implantable	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	System removed due to planned surgery	Appropriate Term/Code Not Available
106315	336330	06/01/2025	AIMD	Analgesic spinal cord electrical stimulation system pulse generator implantable	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	Fever, pain, redness, and swelling at the lead implant site.	Patient Device Interaction Problem
106262	400290	09/04/2025	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Discomfort	Patient Device Interaction Problem
106068	440130	02/02/2025	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Abbott Medical Australia Pty Ltd	Abbott Medical	Fash	Adverse Event Without Identified Device or Use Problem
106070	400373	13/03/2025	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Infection.	Patient Device Interaction Problem
105646	336330	21/12/2024	AIMD	Analgesic spinal cord electrical stimulation system pulse generator implantable	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	Unintended stimulation.	Electrical /Electronic Property Problem
105256	336330	13/12/2024	AIMD	Analgesic spinal cord electrical stimulation system pulse generator implantable	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	Inadequate pain relief.	Electrical /Electronic Property Problem
105104	336330	11/12/2024	AIMD	Analgesic spinal cord electrical stimulation system pulse generator implantable	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	Infection	Adverse Event Without Identified Device or Use Problem
105128	396985	19/02/2025	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Abbott Medical Australia Pty Ltd	Abbott Medical	Patient experienced pain at the IPG site.	Patient Device Interaction Problem
105142	440130	08/01/2025	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Abbott Medical Australia Pty Ltd	Abbott Medical	Difficulties charging the device and the IPG was repositioned.	Electrical /Electronic Property Problem
105063	327091	08/04/2025	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Mainstay Medical Australia Pty Ltd	Mainstay Medical Limited	Therapeutic output failure	Output Problem
105010	327091	06/04/2025	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Mainstay Medical Australia Pty Ltd	Mainstay Medical Limited	Unable to run therapy and an increase in back pain and dysfunction.	Output Problem
105010	327091	06/04/2025	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Mainstay Medical Australia Pty Ltd	Mainstay Medical Limited	Unable to run therapy and an increase in back pain and dysfunction.	Patient Device Interaction Problem
104933	374776	14/02/2025	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	High impedance in implantable pulse generator (IPG) leads.	Electrical /Electronic Property Problem
104915	400290	19/02/2025	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Patient experienced inadequate pain relief.	Patient Device Interaction Problem
104827	336330	04/12/2024	AIMD	Analgesic spinal cord electrical stimulation system pulse generator implantable	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	Explant due to inadequate pain relief.	Patient Device Interaction Problem
104830	327091	04/04/2025	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Mainstay Medical Australia Pty Ltd	Mainstay Medical Limited	Patient unable to run therapy. High impedance.	Electrical /Electronic Property Problem
104784	374776	12/03/2025	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	impedance	Electrical /Electronic Property Problem
104729	327091	01/04/2025	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Mainstay Medical Australia Pty Ltd	Mainstay Medical Limited	Device became loose in the pocket and the patient was unable to run therapy.	Patient Device Interaction Problem
104617	396985	18/01/2025	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Abbott Medical Australia Pty Ltd	Abbott Medical	End of life alert	Appropriate Term/Code Not Available
104455	336330	26/11/2024	AIMD	Analgesic spinal cord electrical stimulation system pulse generator implantable	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	Explant due to inadequate pain relief	Electrical /Electronic Property Problem
104499	400392	10/02/2025	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Sciatica pain	Patient Device Interaction Problem
104429	400392	25/11/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Explantation due to infection	Adverse Event Without Identified Device or Use Problem
104443	400290	25/11/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	sensitivity, discomfort, pain	Adverse Event Without Identified Device or Use Problem
104120	336330	21/11/2024	AIMD	Analgesic spinal cord electrical stimulation system pulse generator implantable	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	Patient death.	Appropriate Term/Code Not Available
104172	336330	21/11/2024	AIMD	Analgesic spinal cord electrical stimulation system pulse generator implantable	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	Frequent charging	Electrical /Electronic Property Problem
104244	374775	23/11/2024	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Ineffective therapy	Electrical /Electronic Property Problem
104244	374775	23/11/2024	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Ineffective therapy	Output Problem
104073	336330	19/11/2024	AIMD	Analgesic spinal cord electrical stimulation system pulse generator implantable	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	discomfort	Adverse Event Without Identified Device or Use Problem
103977	400373	15/11/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Patient experienced inadequate pain relief.	Electrical /Electronic Property Problem
103818	400392	12/11/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Patient experienced a new onset of pain.	Patient Device Interaction Problem
103812	374776	04/03/2025	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Patient experienced numbness and paraplegia resulting in lead explantation.	Adverse Event Without Identified Device or Use Problem
103804	336573	12/11/2024	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	Changes in stimulation	Electrical /Electronic Property Problem
103752	396984	06/03/2025	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Abbott Medical Australia Pty Ltd	Abbott Medical	Infection at the IPG and paddle lead site.	Adverse Event Without Identified Device or Use Problem
103753	374776	16/01/2025	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Ineffective therapy	Output Problem
103711	400373	08/11/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Discomfort and pain	Patient Device Interaction Problem
103699	400392	03/01/2025	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Inadequate stimulation.	Electrical /Electronic Property Problem
103508	400290	11/01/2025	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Reposition due to pain at the Implantable Pulse Generator site.	Mechanical Problem
103482	377339	02/11/2024	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	It was reported that patient experienced ineffective therapy.	Electrical /Electronic Property Problem
103250	336330	24/12/2024	AIMD	Analgesic spinal cord electrical stimulation system pulse generator implantable	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	There is pain at the Closed Loop Stimulator (CLS) implant site.	Patient Device Interaction Problem
103315	336330	06/11/2024	AIMD	Analgesic spinal cord electrical stimulation system pulse generator implantable	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	Pain at the implantation site	Patient Device Interaction Problem
103356	400290	30/10/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	The patient was not getting adequate pain relief from the spinal cord stimulator.	Electrical /Electronic Property Problem
103072	336330	25/10/2024	AIMD	Analgesic spinal cord electrical stimulation system pulse generator implantable	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	Patient dissatisfied with location of CLS at the belt line.	Patient Device Interaction Problem
103025	336573	24/10/2024	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	inadequate pain relief, unintended stimulation, urinary incontinence	Output Problem
102997	374776	27/11/2024	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Revision of the lead due to difficulty to position the leads.	Electrical /Electronic Property Problem
102997	374776	27/11/2024	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Revision of the lead due to difficulty to position the leads.	Mechanical Problem
102985	400392	31/12/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Device did not deliver therapy.	Adverse Event Without Identified Device or Use Problem
102941	330708	21/10/2024	Class III	Implantable spinal cord electrical stimulation system programmer	Nevro Medical Pty Ltd	Nevro Corporation	Ongoing issues regarding programming and pain due to the spinal cord stimulator.	Electrical /Electronic Property Problem
102809	327091	14/01/2025	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Mainstay Medical Australia Pty Ltd	Mainstay Medical Limited	High impedance	Electrical /Electronic Property Problem
102399	327091	14/01/2025	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Mainstay Medical Australia Pty Ltd	Mainstay Medical Limited	Unable to start therapy	Electrical /Electronic Property Problem
102399	327091	14/01/2025	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Mainstay Medical Australia Pty Ltd	Mainstay Medical Limited	Unable to start therapy	Output Problem
102357	400291	12/12/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Inadequate stimulation	Output Problem
102357	400291	12/12/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Inadequate stimulation	Patient Device Interaction Problem
102283	374775	08/01/2025	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Abbott Medical Australia Pty Ltd	Abbott Medical	Migrated and eroding through scalp	Patient Device Interaction Problem
102255	400392	14/11/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Headaches, vertigo, pain, burning sensation and inadequate stimulation	Electrical /Electronic Property Problem
102255	400392	14/11/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Headaches, vertigo, pain, burning sensation and inadequate stimulation	Output Problem
102255	400392	14/11/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Headaches, vertigo, pain, burning sensation and inadequate stimulation	Patient Device Interaction Problem

102200	376449	18/12/2024	AIMD	Analgesic spinal cord electrical stimulation system pulse generator implantable	Abbott Medical Australia Pty Ltd	Abbott Medical	Warmth during charging	Temperature Problem
102199	440130	22/01/2025	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Abbott Medical Australia Pty Ltd	Abbott Medical	communication failure between devices	Connection Problem
102040	336330	27/09/2024	AIMD	Analgesic spinal cord electrical stimulation system pulse generator implantable	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	Device explanted.	Adverse Event Without Identified Device or Use Problem
102050	400291	25/09/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Unexpectedly turned off	Electrical /Electronic Property Problem
101930	400392	23/09/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Patient experienced pain at the pocket site of the implantable pulse generator of the spinal cord stimulator.	Patient Device Interaction Problem
101815	400392	18/09/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Discomfort at implantable pulse generator site.	Patient Device Interaction Problem
101755	396979	10/01/2025	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Abbott Medical Australia Pty Ltd	St Jude Medical	infection at pocket site	Adverse Event Without Identified Device or Use Problem
101776	400392	17/09/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	The implantable pulse generator (IPG) site was red, swollen, as well as visible ooze	Patient Device Interaction Problem
101684	374776	14/09/2024	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Ineffective therapy	Electrical /Electronic Property Problem
101460	385873	31/12/2024	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Patients leads were eroding skin resulting in an infection at the lead and IPG sites.	Patient Device Interaction Problem
101419	374776	06/09/2024	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	The device could not be set into MRI mode, high impedance issues.	Electrical /Electronic Property Problem
101169	336573	06/09/2024	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	Patient experienced discomfort while tilting their head backwards.	Patient Device Interaction Problem
101371	396986	19/12/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Abbott Medical Australia Pty Ltd	St Jude Medical	Explanted due to end of life	Appropriate Term/Code Not Available
101328	400392	04/09/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Revised due to difficulty in charging and dislocation.	Electrical /Electronic Property Problem
101328	400392	04/09/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Revised due to difficulty in charging and dislocation.	Mechanical Problem
101194	374775	07/10/2024	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Skin erosion	Patient Device Interaction Problem
101110	400392	23/09/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Inadequate pain relief. Device was explanted.	Adverse Event Without Identified Device or Use Problem
100843	336330	24/08/2024	AIMD	Analgesic spinal cord electrical stimulation system pulse generator implantable	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	Overstimulation and inadequate pain relief.	Electrical /Electronic Property Problem
100839	336573	23/08/2024	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	Inadequate pain relief, lead migrated.	Patient Device Interaction Problem
100925	400290	22/08/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Inadequate stimulation	Output Problem
100887	374776	02/11/2024	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Ineffective therapy	Material Integrity Problem
100887	374776	02/11/2024	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Ineffective therapy	Output Problem
100694	400392	15/08/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Revision surgery due to patient reporting of inadequate stimulation.	Electrical /Electronic Property Problem
100643	377339	05/12/2024	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Ineffective therapy **Additional Information received from Sponsor 31/12/2024** 26DEC2024: The device has returned. The device analysis is included in this report.	Output Problem
100552	336330	14/08/2024	AIMD	Analgesic spinal cord electrical stimulation system pulse generator implantable	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	Inadequate pain relief	Adverse Event Without Identified Device or Use Problem
100443	396979	09/08/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Abbott Medical Australia Pty Ltd	St Jude Medical	The IPG failed to establish communication with external device post an unrelated surgical procedure.	Communication or Transmission Problem
100244	336330	07/08/2024	AIMD	Analgesic spinal cord electrical stimulation system pulse generator implantable	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	Patient requested explant	No Apparent Adverse Event
100246	336330	07/08/2024	AIMD	Analgesic spinal cord electrical stimulation system pulse generator implantable	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	Inadequate pain relief	Patient Device Interaction Problem
100361	400291	23/10/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Charging issue	Electrical /Electronic Property Problem
100289	400290	06/08/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Inadequate pain relief.	Electrical /Electronic Property Problem
100128	336330	05/08/2024	AIMD	Analgesic spinal cord electrical stimulation system pulse generator implantable	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	Pain, device repositioning	Activation, Positioning or Separation Problem
100182	400290	05/08/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Patient experienced a lack of efficacy from the Spinal Cord Stimulator (SCS) system.	Electrical /Electronic Property Problem
100235	400290	05/08/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Patient experienced inadequate stimulation.	Electrical /Electronic Property Problem
99924	336573	02/08/2024	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	Patient reported symptoms consistent with a nerve injury causing new pain.	Patient Device Interaction Problem
100018	374776	31/08/2024	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Patient experienced ineffective therapy.	Electrical /Electronic Property Problem
100017	327091	06/11/2024	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Mainstay Medical Australia Pty Ltd	Mainstay Medical Limited	It was reported that the patient could not feel stimulation on the left side.	Electrical /Electronic Property Problem
99972	336573	31/07/2024	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	Inadequate pain relief	Patient Device Interaction Problem
99975	400392	17/09/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Pain and blistering at the wound implant site	Adverse Event Without Identified Device or Use Problem
99983	400392	14/10/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	loss of efficacy	Adverse Event Without Identified Device or Use Problem
99895	400392	25/07/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Pain around the implantable pulse generator (IPG) site.	Adverse Event Without Identified Device or Use Problem
99757	374776	24/08/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Abbott Medical Australia Pty Ltd	Abbott Medical	High impedances	Electrical /Electronic Property Problem
99743	400290	21/08/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Device explanted due to inadequate pain relief	Patient Device Interaction Problem
99587	327091	25/10/2024	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Mainstay Medical Australia Pty Ltd	Mainstay Medical Limited	Dural puncture	Use of Device Problem
99618	400290	17/07/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Device explanted due to inadequate pain relief	Patient Device Interaction Problem
99580	400290	16/07/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Inadequate stimulation.	Electrical /Electronic Property Problem
99563	400290	15/07/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Difficulty charging	Electrical /Electronic Property Problem
99398	336330	12/09/2024	AIMD	Analgesic spinal cord electrical stimulation system pulse generator implantable	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	Death	Appropriate Term/Code Not Available
99477	327091	13/09/2024	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Mainstay Medical Australia Pty Ltd	Mainstay Medical Limited	Patient underwent revision surgery due to the progression of out-of-range/high impedance failure of the left lead.	Electrical /Electronic Property Problem
99420	400392	07/10/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Inadequate pain relief and painful sensations	Output Problem
99283	336330	09/07/2024	AIMD	Analgesic spinal cord electrical stimulation system pulse generator implantable	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	Fever and redness experienced at the implant site.	Patient Device Interaction Problem
99364	396979	10/10/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Abbott Medical Australia Pty Ltd	St Jude Medical	pain, explantation of device	Adverse Event Without Identified Device or Use Problem
99250	396979	24/08/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Abbott Medical Australia Pty Ltd	St Jude Medical	Pain, device has tilted.	Appropriate Term/Code Not Available
99250	396979	24/08/2024	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	St Jude Medical	Pain, device has tilted.	Mechanical Problem
99251	374776	26/10/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Abbott Medical Australia Pty Ltd	Abbott Medical	The patient was experiencing ineffective therapy.	Electrical /Electronic Property Problem
99125	336573	04/07/2024	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	A patient implanted with an Evoke Spinal Cord Stimulation (SCS) System was noted to have an infection at their midline wound.	Patient Device Interaction Problem

99207	400290	03/07/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Infection.	Adverse Event Without Identified Device or Use Problem
99211	400290	03/07/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Burning sensation pain at the implantable pulse generator. Patient was prescribed lidocaine patches for local pain relief.	Adverse Event Without Identified Device or Use Problem
99116	410450	28/06/2024	Class IIb	Analgesic spinal cord electrical stimulation system pulse generator	Biotronik Australia Pty Ltd	Biotronik SE & Co KG	Multiple issues.	Electrical /Electronic Property Problem
99116	410450	28/06/2024	Class IIb	Analgesic spinal cord electrical stimulation system pulse generator	Biotronik Australia Pty Ltd	Biotronik SE & Co KG	Multiple issues.	Human-Device Interface Problem
99079	400392	28/06/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Patient experienced swelling at device site and difficulty charging device.	Electrical /Electronic Property Problem
99079	400392	28/06/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Patient experienced swelling at device site and difficulty charging device.	Patient Device Interaction Problem
99002	400392	27/06/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Frequent charging of spinal cord stimulation device. Surgical intervention and device was replaced.	Electrical /Electronic Property Problem
99015	400392	11/09/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Cellulitis experienced post procedure.	Appropriate Term/Code Not Available
99018	400392	27/06/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Insufficient efficacy and pain relief from the spinal cord stimulation system.	Appropriate Term/Code Not Available
98906	336573	27/06/2024	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	Lead revision for additional coverage.	Patient Device Interaction Problem
98910	400392	26/06/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Pain	Patient Device Interaction Problem
98827	374776	10/08/2024	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	It was reported that patient experienced ineffective therapy.	Electrical /Electronic Property Problem
98827	374776	10/08/2024	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	It was reported that patient experienced ineffective therapy.	Patient Device Interaction Problem
98830	385873	14/09/2024	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Patient experienced ineffective therapy, uncomfortable stimulation, and involuntary movements.	Electrical /Electronic Property Problem
98698	400290	20/06/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Spinal cord stimulator devices were unable to provide pain relief.	Electrical /Electronic Property Problem
98553	400392	03/10/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Inadequate stimulation	Electrical /Electronic Property Problem
98558	400392	18/06/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Swelling	Adverse Event Without Identified Device or Use Problem
98541	384012	12/10/2024	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Ineffective therapy	Electrical /Electronic Property Problem
98541	384012	12/10/2024	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Ineffective therapy	Output Problem
98440	377339	14/06/2024	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Discomfort	Adverse Event Without Identified Device or Use Problem
98109	336573	17/07/2024	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	Patient reported stimulation issues. A lead had migrated.	Patient Device Interaction Problem
98289	396987	09/10/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Abbott Medical Australia Pty Ltd	Abbott Medical	Ooze	Adverse Event Without Identified Device or Use Problem
98318	400373	12/06/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Pain and ineffective therapy experienced.	Electrical /Electronic Property Problem
98171	377339	07/06/2024	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	High impedance due to lead migration.	Electrical /Electronic Property Problem
98171	377339	07/06/2024	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	High impedance due to lead migration.	Patient Device Interaction Problem
98169	336573	05/08/2024	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	Impaired healing at their midline incision	Patient Device Interaction Problem
98115	400392	16/08/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	vomiting	Adverse Event Without Identified Device or Use Problem
98049	400392	03/10/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Inadequate stimulation and difficulty charging	Electrical /Electronic Property Problem
98051	400392	19/06/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Difficulty charging and communicating with remote	Communication or Transmission Problem
98051	400392	19/06/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Difficulty charging and communicating with remote	Electrical /Electronic Property Problem
97873	376449	29/08/2024	AIMD	Analgesic spinal cord electrical stimulation system pulse generator implantable	Abbott Medical Australia Pty Ltd	Abbott Medical	Revision due to high impedances and ineffective therapy.	Electrical /Electronic Property Problem
97896	440130	21/07/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Abbott Medical Australia Pty Ltd	Abbott Medical	Infection	Adverse Event Without Identified Device or Use Problem
97916	400290	30/05/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Device was repositioned due to the patient having difficulty charging the Device and patient experiencing pain and discomfort at the IPG site.	Electrical /Electronic Property Problem
97911	392267	31/07/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Medtronic Australasia Pty Ltd	Medtronic Inc	seizure	Patient Device Interaction Problem
97787	400290	17/07/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Loss of pain relief.	Appropriate Term/Code Not Available
97603	396982	21/05/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Abbott Medical Australia Pty Ltd	St Jude Medical	Failed to establish communication with external device	Communication or Transmission Problem
97619	400290	17/09/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Loss of therapy.	Output Problem
97621	400392	11/06/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Difficulty charging	Electrical /Electronic Property Problem
97585	400290	13/08/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Loss of therapy	Electrical /Electronic Property Problem
97420	336330	19/07/2024	AIMD	Analgesic spinal cord electrical stimulation system pulse generator implantable	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	The patient's wound reopened, and an infection was confirmed.	Patient Device Interaction Problem
97575	327091	07/09/2024	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Mainstay Medical Australia Pty Ltd	Mainstay Medical Limited	Specialist could not elicit any muscle twitch response bilaterally.	Electrical /Electronic Property Problem
97525	396979	17/05/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Abbott Medical Australia Pty Ltd	St Jude Medical	Migrated	Patient Device Interaction Problem
97480	400290	14/08/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	communication failure	Communication or Transmission Problem
97501	400392	14/08/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	inadequate stimulation, explantation	Adverse Event Without Identified Device or Use Problem
97446	327091	09/08/2024	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Mainstay Medical Australia Pty Ltd	Mainstay Medical Limited	Progression of out-of-range/high impedance failure.	Electrical /Electronic Property Problem
97378	400392	13/05/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Swelling and redness	Patient Device Interaction Problem
97383	400392	13/05/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Pain.	Appropriate Term/Code Not Available
97326	400373	10/05/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Inadequate stimulation	Patient Device Interaction Problem
97223	400290	07/05/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Pain	Appropriate Term/Code Not Available
97190	400392	06/05/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Implant pain	Patient Device Interaction Problem
97182	400291	05/05/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Sudden onset of pain.	Patient Device Interaction Problem
97181	400291	03/05/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	The lead was abandoned after encountering resistance, when it was removed the coating of the lead had been breached.	Material Integrity Problem
97042	400290	17/05/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Inadequate stimulation	Patient Device Interaction Problem

97043	400392	28/06/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Pain.	Adverse Event Without Identified Device or Use Problem
96999	377339	21/08/2024	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Ineffective therapy and oozing at implant site experienced.	Electrical /Electronic Property Problem
96988	327091	09/08/2024	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Mainstay Medical Australia Pty Ltd	Mainstay Medical Limited	Patient was having difficulty activating the device.	Activation, Positioning or Separation Problem
96988	327091	09/08/2024	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Mainstay Medical Australia Pty Ltd	Mainstay Medical Limited	Patient was having difficulty activating the device.	Electrical /Electronic Property Problem
96869	374775	17/08/2024	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	It was reported that the patient experienced ineffective stimulation/ decrease on therapy strength.	Electrical /Electronic Property Problem
96760	327091	05/07/2024	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Mainstay Medical Australia Pty Ltd	Mainstay Medical Limited	high impedance	Electrical /Electronic Property Problem
96598	400392	26/04/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Inadequate stimulation	Patient Device Interaction Problem
96613	214839	15/04/2024	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Medtronic Australasia Pty Ltd	Medtronic Inc	The patient experienced the chronic back pain and depression post the device ceased to work.	Appropriate Term/Code Not Available
96613	214839	15/04/2024	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Medtronic Australasia Pty Ltd	Medtronic Inc	The patient experienced the chronic back pain and depression post the device ceased to work.	Electrical /Electronic Property Problem
96588	374776	08/06/2024	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Motor loss .	Appropriate Term/Code Not Available
96566	400392	25/07/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Headaches due to overstimulation.	Electrical /Electronic Property Problem
96584	400392	17/05/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Infection	Adverse Event Without Identified Device or Use Problem
96529	400290	11/04/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	The inadequate stimulation was experienced.	Electrical /Electronic Property Problem
96480	396979	08/06/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Abbott Medical Australia Pty Ltd	St Jude Medical	Discomfort at the IPG side due to placement	Activation, Positioning or Separation Problem
96335	400392	08/05/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Device explantation due to infection at IPG site	Patient Device Interaction Problem
96316	400392	16/04/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	The patient experienced a hematoma in the IPG pocket with pain, swelling and edema around the IPG site.	Appropriate Term/Code Not Available
96321	400392	04/04/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Patient had a fall and experienced pain at the implantable pulse generator site which was unable to charge.	Appropriate Term/Code Not Available
96321	400392	04/04/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Patient had a fall and experienced pain at the implantable pulse generator site which was unable to charge.	Electrical /Electronic Property Problem
96321	400392	04/04/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Patient had a fall and experienced pain at the implantable pulse generator site which was unable to charge.	Patient Device Interaction Problem
96219	374776	22/06/2024	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	high impedance	Electrical /Electronic Property Problem
96219	374776	22/06/2024	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	high impedance	Material Integrity Problem
96217	327091	02/07/2024	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Mainstay Medical Australia Pty Ltd	Mainstay Medical Limited	Revision due to out of range/high impedance with lost therapy.	Electrical /Electronic Property Problem
96196	336573	29/03/2024	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	Migration of lead.	Patient Device Interaction Problem
96129	400392	27/03/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	IPG pocket revised due to pain at the Implantable Pulse Generator (IPG) pocket site. The patients' second IPG was explanted and upgraded. Two leads were repositioned due to migration and inadequate stimulation.	Electrical /Electronic Property Problem
96129	400392	27/03/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	IPG pocket revised due to pain at the Implantable Pulse Generator (IPG) pocket site. The patients' second IPG was explanted and upgraded. Two leads were repositioned due to migration and inadequate stimulation.	Patient Device Interaction Problem
95912	336573	19/04/2024	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	Patient experienced unilateral lower leg swelling and tenderness.	Patient Device Interaction Problem
95975	396979	22/03/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Abbott Medical Australia Pty Ltd	St Jude Medical	Hospitalisation confirmed deep vein thrombosis.	Adverse Event Without Identified Device or Use Problem
95976	396982	13/04/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Abbott Medical Australia Pty Ltd	St Jude Medical	Patient experienced pain at IPG site.	Patient Device Interaction Problem
95744	336330	19/03/2024	AIMD	Analgesic spinal cord electrical stimulation system pulse generator implantable	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	Pain at implant site and eroding through skin.	Patient Device Interaction Problem
95841	400392	30/05/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Headache following the implant procedure	Insufficient Information
95859	400392	05/04/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Inadequate Stimulation	Electrical /Electronic Property Problem
95723	327091	07/06/2024	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Mainstay Medical Australia Pty Ltd	Mainstay Medical Limited	Device revision due to pain experienced at device implant site	Patient Device Interaction Problem
95640	374776	01/04/2024	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	out-of-range/high-impedance failure.	Electrical /Electronic Property Problem
95572	336573	13/03/2024	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	Device replacement due to high impedance	Electrical /Electronic Property Problem
95612	336573	13/03/2024	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	During a trial procedure for the device, the patient experienced respiratory arrest. As a result, the lead was removed due to close proximity of the second lead. After the procedure during programming session, the patient reported experiencing a headache and undesirable stimulation. The managing physician advised to continue the trial for the Device. The patient was discharged the following day.	Patient Device Interaction Problem
95612	336573	13/03/2024	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	During placement, the physician encountered difficulty in advancing the lead. Extra force was used and the lead was pulled back resulting in breakage of lead. X-ray imaging showed 2 distal electrodes of the lead within the patient and was left in vivo. A new lead was used to complete the lead placement for trial procedure.	Activation, Positioning or Separation Problem
95612	336573	13/03/2024	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	During placement, the physician encountered difficulty in advancing the lead. Extra force was used and the lead was pulled back resulting in breakage of lead. X-ray imaging showed 2 distal electrodes of the lead within the patient and was left in vivo. A new lead was used to complete the lead placement for trial procedure.	Material Integrity Problem
95607	400392	05/04/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Extra force was used and the lead was pulled back resulting in breakage of lead. X-ray imaging showed 2 distal electrodes of the lead within the patient and was left in vivo. A new lead was used to complete the lead placement for trial procedure.	Patient Device Interaction Problem
95457	281250	24/05/2024	Class III	Neural-tissue electrical stimulation lead adaptor	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Numbness and pain in left arm	Patient Device Interaction Problem
95362	336330	17/04/2024	AIMD	Analgesic spinal cord electrical stimulation system pulse generator implantable	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	Cyst formation at the adapter site.	Patient Device Interaction Problem
95364	374776	08/06/2024	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Uncomfortable stimulation experienced. High impedance but within range.	Electrical /Electronic Property Problem
95051	336573	16/04/2024	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	Ineffective therapy	Electrical /Electronic Property Problem
95206	400392	28/02/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Fever after removal of the device. Patient was admitted to hospital, antibiotics and narcotic were administered.	Adverse Event Without Identified Device or Use Problem
95178	400392	27/02/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	No pain relief experienced.	Electrical /Electronic Property Problem
95128	400392	07/05/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Inadequate stimulation	Patient Device Interaction Problem
95130	400392	28/02/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Patient experiencing inadequate pain relief and device was unable to charge. IPG had flipped in the pocket site and paddle lead had migrated to the right side. Paddle leads were explanted and replaced and patient underwent IPG repositional surgery.	Electrical /Electronic Property Problem
95130	400392	28/02/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Patient experiencing inadequate pain relief and device was unable to charge. IPG had flipped in the pocket site and paddle lead had migrated to the right side. Paddle leads were explanted and replaced and patient underwent IPG repositional surgery.	Patient Device Interaction Problem
94944	336573	24/04/2024	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	A patient reported inadequate pain relief. Revision was performed due to lead migration.	Patient Device Interaction Problem
95030	400392	22/02/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Charging Issue	Electrical /Electronic Property Problem

95012	374776	25/05/2024	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Post-operative infection	Adverse Event Without Identified Device or Use Problem
94884	400392	19/02/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Difficulty charging device. Discomfort at implantation site due to device flipping in the pocket.	Electrical /Electronic Property Problem
94884	400392	19/02/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Difficulty charging device. Discomfort at implantation site due to device flipping in the pocket.	Patient Device Interaction Problem
94652	327091	11/04/2024	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Mainstay Medical Australia Pty Ltd	Mainstay Medical Limited	Difficulty activating device and high impedance. Revision surgery to replace leads.	Activation, Positioning or Separation Problem
94652	327091	11/04/2024	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Mainstay Medical Australia Pty Ltd	Mainstay Medical Limited	Difficulty activating device and high impedance. Revision surgery to replace leads.	Electrical /Electronic Property Problem
94531	374775	13/04/2024	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Explantation of device due to ineffective therapy	Patient Device Interaction Problem
94511	400392	07/02/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Reported that the patient experienced difficulty charging the implantable pulse generator.	Activation, Positioning or Separation Problem
94511	400392	07/02/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Reported that the patient experienced difficulty charging the implantable pulse generator.	Electrical /Electronic Property Problem
94412	385873	23/04/2024	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Ineffective stimulation due to high impedances.	Electrical /Electronic Property Problem
94353	400290	16/04/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Minimal relief	Patient Device Interaction Problem
94272	396982	17/02/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Abbott Medical Australia Pty Ltd	St Jude Medical	Device explanted due to Device eroding the skin.	Appropriate Term/Code Not Available
94251	400392	15/04/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Bluetooth fault causing internal resets	Communication or Transmission Problem
94251	400392	15/04/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Bluetooth fault causing internal resets	Electrical /Electronic Property Problem
94230	327091	30/03/2024	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Mainstay Medical Australia Pty Ltd	Mainstay Medical Limited	Device replacement due to high impedance	Electrical /Electronic Property Problem
94167	400392	24/01/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Bluetooth fault code when charging the device battery.	Electrical /Electronic Property Problem
94167	400392	24/01/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Bluetooth fault code when charging the device battery.	Protective Measures Problem
94136	400392	23/01/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	A severely infected seroma around the IPG site.	Appropriate Term/Code Not Available
94004	400373	29/03/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Pain and discomfort around the site of the implantation due to migration of the device.	Patient Device Interaction Problem
93943	400392	29/02/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Infection at the Implantable Pulse Generator site of the Stimulator.	Appropriate Term/Code Not Available
93829	377339	26/01/2024	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	The patient experienced pain and swelling at the Implantable Pulse Generator (IPG) site of the Spinal Cord Stimulator (SCS) system and difficulty charging.	Electrical /Electronic Property Problem
93809	400291	24/01/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	The patient experienced pain and swelling at the Implantable Pulse Generator (IPG) site of the Spinal Cord Stimulator (SCS) system and difficulty charging.	Electrical /Electronic Property Problem
93809	400291	24/01/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	The patient experienced pain and swelling at the Implantable Pulse Generator (IPG) site of the Spinal Cord Stimulator (SCS) system and difficulty charging.	Patient Device Interaction Problem
93810	400392	29/02/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Device repositioned due to the patient experiencing discomfort.	Appropriate Term/Code Not Available
93755	400290	06/01/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	It was reported that the patient was experiencing frequent charging of the Spinal Cord Stimulation (SCS) Implantable Pulse Generator.	Electrical /Electronic Property Problem
93661	400392	02/01/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Following a spinal cord stimulation (SCS) implant procedure, the patient presented to the hospital with vomiting and a severe headache.	Adverse Event Without Identified Device or Use Problem
93589	400392	08/03/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Device explanted as it was also reported that the stimulation was causing wind-up pain.	Electrical /Electronic Property Problem
93490	400392	21/12/2023	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Pain experienced at the implant pocket site.	Appropriate Term/Code Not Available
93404	374776	10/04/2024	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Swelling.	Patient Device Interaction Problem
93375	400392	19/12/2023	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Revision surgery due to inadequate stimulation.	Electrical /Electronic Property Problem
93365	389797	07/05/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Medtronic Australasia Pty Ltd	Medtronic Inc	Premature battery depletion	Electrical /Electronic Property Problem
93308	377339	08/02/2024	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Explant due to ineffective stimulation due to lead migration and the scar tissue.	Electrical /Electronic Property Problem
93308	377339	08/02/2024	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Explant due to ineffective stimulation due to lead migration and the scar tissue.	Patient Device Interaction Problem
93200	400392	19/01/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Inadequate stimulation.	Electrical /Electronic Property Problem
93092	336330	12/12/2023	AIMD	Analgesic spinal cord electrical stimulation system pulse generator implantable	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	Explantation due to infection.	Insufficient Information
92929	374776	21/12/2023	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	High impedance.	Electrical /Electronic Property Problem
92912	400392	19/02/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Patient experienced a zapping sensation at the implantable pulse generator site (IPG) only when the stimulation was on. The patient's device was reprogrammed and new programs were added.	Appropriate Term/Code Not Available
92799	336573	05/12/2023	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	Patient reported inadequate pain relief.	Mechanical Problem
92873	400290	16/02/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Discomfort in the lower back, numbness and tingling in the arm when the device was turned on.	Appropriate Term/Code Not Available
92710	374775	08/02/2024	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Post operative pain experienced.	Appropriate Term/Code Not Available
92363	385873	15/11/2023	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	The lead was fractured.	Material Integrity Problem
92193	336330	13/01/2024	AIMD	Analgesic spinal cord electrical stimulation system pulse generator implantable	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	A small area of the implant site wound was noticed to be unhealed.	Patient Device Interaction Problem
92243	400373	10/11/2023	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Paint at the implantable pulse generator (IPG) site due to primary cell IPG size.	Patient Device Interaction Problem
92206	400290	08/12/2023	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Migration.	Patient Device Interaction Problem
92189	385873	09/11/2023	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Incomplete removal of leads during explant surgery.	Material Integrity Problem
92194	327091	05/01/2024	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Mainstay Medical Australia Pty Ltd	Mainstay Medical Limited	Revision surgery to replace right lead due to high impedances.	Electrical /Electronic Property Problem
92175	336573	09/11/2023	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	Lead explanted due to migration.	Patient Device Interaction Problem
92162	400290	22/01/2024	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Revision procedure to explant leads.	Appropriate Term/Code Not Available
92149	374776	23/11/2023	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	The patient experienced uncomfortable stimulation/new pain during trial. High impedance on the lead.	Electrical /Electronic Property Problem
92058	336330	06/11/2023	AIMD	Analgesic spinal cord electrical stimulation system pulse generator implantable	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	Device was explanted due to a planned cervical spine surgery. The Healthcare professional did not allege any device issue.	Appropriate Term/Code Not Available
92078	374776	09/11/2023	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	The patient experienced ineffective therapy.	Electrical /Electronic Property Problem
92079	374776	07/12/2023	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	The patient experienced ineffective therapy.	Output Problem
91983	336573	03/11/2023	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	Revision surgery due to unintended stimulation, low impedance and lead migration.	Electrical /Electronic Property Problem
91983	336573	03/11/2023	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	Revision surgery due to unintended stimulation, low impedance and lead migration.	Patient Device Interaction Problem
92023	400392	02/11/2023	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Intermittent zapping, pain and inadequate pain relief.	Adverse Event Without Identified Device or Use Problem
91944	374776	21/12/2023	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	High impedance and pain as a result of lead fracture.	Appropriate Term/Code Not Available

91944	374776	21/12/2023	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	High impedance and pain as a result of lead fracture.	Electrical /Electronic Property Problem
91869	400392	27/10/2023	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Surgical revision due to pain.	Appropriate Term/Code Not Available
91870	400392	27/10/2023	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Explanation of IPG due to migration, becoming superficial with in adequate stimulation.	Electrical /Electronic Property Problem
91870	400392	27/10/2023	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Explanation of IPG due to migration, becoming superficial with in adequate stimulation.	Material Integrity Problem
91870	400392	27/10/2023	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Explanation of IPG due to migration, becoming superficial with in adequate stimulation.	Patient Device Interaction Problem
91858	374776	04/05/2024	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Loss of Therapy	Electrical /Electronic Property Problem
91787	392267	25/10/2023	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Medtronic Australasia Pty Ltd	Medtronic Inc	Patient passed away.	Appropriate Term/Code Not Available
91699	400290	23/10/2023	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Discomfort experienced, IPG had tilted in the pocket site.	Patient Device Interaction Problem
91666	396987	02/12/2023	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Abbott Medical Australia Pty Ltd	Abbott Medical	It was reported the patient is experiencing pain at the IPG site due to the lateral edge of the IPG closer to the skin surface	Mechanical Problem
91590	374776	23/11/2023	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Skin breakdown at the battery site and hematoma at the lead site.	Adverse Event Without Identified Device or Use Problem
91486	396979	10/11/2023	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Abbott Medical Australia Pty Ltd	St Jude Medical	Heat experienced at the IPG site during an MRI scan.	Temperature Problem
91415	374775	12/10/2023	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	The patient's lead had migrated.	Patient Device Interaction Problem
91326	374775	03/11/2023	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Patient had no pain coverage	Appropriate Term/Code Not Available
91242	374776	05/10/2023	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Ineffective therapy and did not charge their device.	Electrical /Electronic Property Problem
91200	400392	04/10/2023	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Infection	Appropriate Term/Code Not Available
91133	377339	23/01/2024	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	The device was explanted due to ineffective therapy and inadequate coverage.	Electrical /Electronic Property Problem
91120	327091	05/12/2023	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Mainstay Medical Australia Pty Ltd	Mainstay Medical Limited	The patient could not use the device for therapy and found multiple high impedances of the right lead and one electrode of the left lead.	Electrical /Electronic Property Problem
91033	396982	11/11/2023	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Abbott Medical Australia Pty Ltd	St Jude Medical	Patient experienced pain at the device site.	Appropriate Term/Code Not Available
91026	396979	27/09/2023	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Abbott Medical Australia Pty Ltd	St Jude Medical	The device stopped working near its end of life. Or Premature Battery depletion.	Electrical /Electronic Property Problem
91001	400290	27/09/2023	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	It was reported that the patient did not receive pain relief from therapy.	Electrical /Electronic Property Problem
90960	400392	26/09/2023	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Patient's two incision sites appeared to be a bit red and inflamed.	Adverse Event Without Identified Device or Use Problem
90761	396987	14/10/2023	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Abbott Medical Australia Pty Ltd	Abbott Medical	Patient experienced a hematoma at the IPG site resulting in pain at the IPG site.	Patient Device Interaction Problem
90687	396982	12/10/2023	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Abbott Medical Australia Pty Ltd	St Jude Medical	It was reported the patient underwent shoulder surgery and the IPG was placed in surgery mode. The IPG was unable to communicate. Surgical intervention may take place at a later date to address the issue.	Communication or Transmission Problem
90575	336573	11/09/2023	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	Migration of lead inside patient.	Mechanical Problem
90495	400290	07/09/2023	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Constant pain at the Implantable Pulse Generator (IPG) site.	Appropriate Term/Code Not Available
90445	385873	20/10/2023	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Ineffective therapy experienced, high impedances recorded.	Electrical /Electronic Property Problem
90384	374776	15/09/2023	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Unable to enter MRI mode.	Electrical /Electronic Property Problem
90387	327091	31/10/2023	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Mainstay Medical Australia Pty Ltd	Mainstay Medical Limited	Difficulty in activating the device due to out of range/ high impedances.	Electrical /Electronic Property Problem
90346	336573	20/09/2023	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	The patient reported not receiving adequate pain coverage.	Electrical /Electronic Property Problem
90346	336573	20/09/2023	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	The patient reported not receiving adequate pain coverage.	Patient Device Interaction Problem
90297	336330	01/09/2023	AIMD	Analgesic spinal cord electrical stimulation system pulse generator implantable	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	Revision due to unavailable contacts.	Electrical /Electronic Property Problem
90310	385873	31/08/2023	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	It was reported the patient's L3 DRG lead had migrated. Surgical intervention was undertaken during which the lead was explanted, and patient's other 2 leads remain implanted.	Patient Device Interaction Problem
90283	400392	30/08/2023	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Discharge at site of device signifying potential infection.	Patient Device Interaction Problem
90174	400392	25/08/2023	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Spinal cord stimulation (SCS) patient was experiencing discomfort due to the Implantable Pulse Generator (IPG) tilting forward in the IPG pocket.	Mechanical Problem
90056	336330	14/09/2023	AIMD	Analgesic spinal cord electrical stimulation system pulse generator implantable	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	The patient reported sharp sensations, buzzing sensations, and cramping sensations in days following removal of leads surgery.	Electrical /Electronic Property Problem
90055	336573	07/09/2023	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	Secondary revision surgery as during the first revision, patient underwent monopolar electrosurgery causing lead damage.	Material Integrity Problem
90081	400392	22/08/2023	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Patient experienced multiple complications following insertion of implantable pulse generator.	Patient Device Interaction Problem
90001	400290	13/10/2023	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Device explanted due to inadequate stimulation.	Electrical /Electronic Property Problem
89879	374776	15/08/2023	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	It was reported the patient experienced inadequate stimulation with their spinal cord stimulator system.	Electrical /Electronic Property Problem
89707	396982	15/08/2023	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Abbott Medical Australia Pty Ltd	St Jude Medical	Pain at the IPG site.	Appropriate Term/Code Not Available
89733	400392	09/08/2023	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	The patient experienced pain at the Implantable Pulse Generator (IPG) site, all the back, and headaches, the patient had an infection and sepsis at the IPG site.	Appropriate Term/Code Not Available
89649	327091	03/10/2023	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Mainstay Medical Australia Pty Ltd	Mainstay Medical Limited	Electrodes out of range	Electrical /Electronic Property Problem
89582	336573	29/08/2023	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	Post implant of two leads, one of the leads was removed as it was providing unneeded stim and not recruiting the correct dermatome for the patient.	Electrical /Electronic Property Problem
89402	336330	03/08/2023	AIMD	Analgesic spinal cord electrical stimulation system pulse generator implantable	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	The second lead remains implanted however patient complained about a severe headache and a painful right leg.	Adverse Event Without Identified Device or Use Problem
89596	400290	13/10/2023	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Burning sensation and pain at the pocket site was reported. The device had migrated.	Patient Device Interaction Problem
89588	374776	03/08/2023	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Ineffective stimulation due to high impedances and the system was explanted.	Electrical /Electronic Property Problem
89572	327091	02/09/2023	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Mainstay Medical Australia Pty Ltd	Mainstay Medical Limited	Patient only felt stimulation on the right side and was unable to reach perception or muscle activation. X-ray images revealed left lead migration.	Electrical /Electronic Property Problem
89572	327091	02/09/2023	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Mainstay Medical Australia Pty Ltd	Mainstay Medical Limited	Patient only felt stimulation on the right side and was unable to reach perception or muscle activation. X-ray images revealed left lead migration.	Patient Device Interaction Problem
89520	396979	07/11/2023	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Abbott Medical Australia Pty Ltd	St Jude Medical	Patient is unable to turn on therapy due to device inability to communicate with external devices.	Communication or Transmission Problem
89421	336573	22/09/2023	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	A malfunction across multiple electrodes on both leads was reported.	Electrical /Electronic Property Problem
89422	336573	22/09/2023	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	During follow-up, lead impedance testing confirmed a malfunction across multiple electrodes.	Appropriate Term/Code Not Available
89333	400392	21/09/2023	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	It was reported that the patient experienced pain at the Implantable Pulse Generator pocket site.	Patient Device Interaction Problem
89244	385873	17/11/2023	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Ineffective therapy	Electrical /Electronic Property Problem
89200	400392	20/09/2023	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Spinal cord stimulation patient never received relief and underwent replacement.	Adverse Event Without Identified Device or Use Problem

89117	327091	13/09/2023	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Mainstay Medical Australia Pty Ltd	Mainstay Medical Limited	Out-of-range lead impedance.	Electrical /Electronic Property Problem
89006	396982	18/08/2023	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Abbott Medical Australia Pty Ltd	St Jude Medical	Patient death.	Appropriate Term/Code Not Available
88963	377339	18/08/2023	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Patient experienced pain at the lead site and tingling sensation and lead migration was confirmed via scans.	Patient Device Interaction Problem
88877	376449	03/08/2023	AIMD	Analgesic spinal cord electrical stimulation system pulse generator implantable	Abbott Medical Australia Pty Ltd	Abbott Medical	The patient did not recharge the IPG and the IPG became inoperable.	Use of Device Problem
88894	400392	06/07/2023	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Patient developed an infection at the surgical incision sites	Patient Device Interaction Problem
88895	400392	06/07/2023	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Patient experienced an overall unwell feeling suspected due to infection near the implant	Patient Device Interaction Problem
88798	400392	18/09/2023	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	The spinal cord stimulation (SCS) patient experienced inadequate stimulation wherein causing pain in their left lower extremity at night.	Electrical /Electronic Property Problem
88804	400392	19/09/2023	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Patient experienced difficulty charging the Implantable Pulse Generator.	Activation, Positioning or Separation Problem
88801	385873	14/09/2023	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	The patient experienced numbness and tingling post procedure.	Appropriate Term/Code Not Available
88770	385873	29/08/2023	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Lead migrated in patient causing ineffective therapy.	Patient Device Interaction Problem
88704	336573	26/07/2023	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	Lead migration and loss of coverage	Electrical /Electronic Property Problem
88705	336573	26/07/2023	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	Device stimulation stopped during exercise.	Electrical /Electronic Property Problem
88705	336573	26/07/2023	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	Device stimulation stopped during exercise.	Patient Device Interaction Problem
88687	400392	11/09/2023	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Patient experienced inadequate stimulation and an increase in their pre-existing lower extremity pain.	Electrical /Electronic Property Problem
88650	400392	31/08/2023	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Difficulty charging and communicating with the implantable pulse generator.	Electrical /Electronic Property Problem
88638	374776	19/07/2023	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Patient experienced burning pain in the right calf and foot.	Adverse Event Without Identified Device or Use Problem
88568	374775	14/09/2023	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Patient's lead had high impedances resulting in ineffective therapy.	Electrical /Electronic Property Problem
88449	400392	19/06/2023	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Difficulty charging.	Electrical /Electronic Property Problem
88269	336330	14/06/2023	AIMD	Analgesic spinal cord electrical stimulation system pulse generator implantable	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	Patient has not had any effect of therapy since implantation.	Electrical /Electronic Property Problem
88285	400392	25/07/2023	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	The patient experienced inadequate stimulation.	Electrical /Electronic Property Problem
88251	374775	28/06/2023	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	It was reported that both of the patient's leads exhibited high impedances.	Electrical /Electronic Property Problem
88236	400392	09/06/2023	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Revision due to the IPG being loose in the pocket site.	Patient Device Interaction Problem
88093	377340	14/10/2023	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Infection at the lead site	Insufficient Information
88052	384012	17/06/2023	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Patient was experiencing ineffective stimulation due to high impedances.	Electrical /Electronic Property Problem
88027	400373	01/06/2023	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	The device flares up a pre-existing condition.	Patient Device Interaction Problem
88041	400392	25/07/2023	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	The Device was explanted as patient was experiencing pain and bruising at the site. The patient stated that there wasn't anything wrong with the device and he did experience pain relief from the system, but he believed that the pain was due to the physicians' placement of the device.	Appropriate Term/Code Not Available
87982	400290	31/05/2023	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	It was reported that the patient was experiencing redness, swelling and pain at the spinal cord stimulation implantable pulse stimulator site.	Adverse Event Without Identified Device or Use Problem
87985	400392	27/07/2023	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Spinal cord stimulation (SCS) patient experienced discomfort at the implantable pulse generator (IPG) site.	Patient Device Interaction Problem
87797	396979	15/07/2023	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Abbott Medical Australia Pty Ltd	St Jude Medical	Infection at implantable pulse generator site.	Appropriate Term/Code Not Available
87622	400392	12/06/2023	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Patient experienced discomfort at the Implantable Pulse Generator (IPG) belt line site.	Patient Device Interaction Problem
87563	396982	15/06/2023	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Abbott Medical Australia Pty Ltd	St Jude Medical	It was reported that following an unrelated surgical procedure where it is unknown if the IPG was placed into surgery mode, the IPG became unable to communicate with external devices.	Communication or Transmission Problem
87562	377339	24/08/2023	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Patient experienced ineffective therapy. X-ray imaging showed dislodgement and significant twisting of the distal end of the lead.	Material Integrity Problem
87562	377339	24/08/2023	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Patient experienced ineffective therapy. X-ray imaging showed dislodgement and significant twisting of the distal end of the lead.	Mechanical Problem
87525	374776	17/06/2023	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Patient experienced ineffective therapy. One lead noted to have migrated.	Mechanical Problem
87315	400290	05/05/2023	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	The patient was not receiving pain relief.	Electrical /Electronic Property Problem
87320	400392	24/07/2023	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Inadequate stimulation.	Electrical /Electronic Property Problem
87282	377339	28/06/2023	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	It was reported that the patient experienced an infection at the lead incision site.	Appropriate Term/Code Not Available
86807	374776	22/05/2023	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	It was reported that the patient experienced undesired nerve stimulation which caused muscular spasms.	Electrical /Electronic Property Problem
86808	385873	19/05/2023	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Patient experienced ineffective therapy.	Adverse Event Without Identified Device or Use Problem
86776	374776	04/07/2023	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Lead was confirmed to be fractured.	Material Integrity Problem
86735	374776	26/05/2023	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	The patient experience ineffective therapy.	Electrical /Electronic Property Problem
86695	327091	11/06/2023	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Mainstay Medical Australia Pty Ltd	Mainstay Medical Limited	Patient experienced intense pain when getting down on hands and knees to reach under a cabinet.	Mechanical Problem
86680	384012	29/07/2023	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	The lead migrated resulting in ineffective therapy and subsequent surgical intervention.	Patient Device Interaction Problem
86644	400392	06/04/2023	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	It was reported the spinal cord stimulation (SCS) patient experienced a loss of pain coverage. The physician assessed the device had migrated; attempts to reprogram the device were unsuccessful.	Patient Device Interaction Problem
86573	374776	12/04/2023	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Patient experienced ineffective therapy and required additional unrelated surgical interventions.	Patient Device Interaction Problem
86488	400392	03/04/2023	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	IPG was repositioned as patient experienced difficulty charging.	Connection Problem
86471	374776	12/04/2023	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	It was reported that following the implant procedure, the patient experienced a headache which worsened over several days.	Appropriate Term/Code Not Available
86183	385873	14/04/2023	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Ineffective stimulation due to lead migration.	Patient Device Interaction Problem
86188	377340	17/07/2023	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Patient experienced an extradural hematoma after straining to evacuate their bowels.	Adverse Event Without Identified Device or Use Problem
86090	385873	05/05/2023	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Ineffective therapy.	Electrical /Electronic Property Problem
85915	374775	14/03/2023	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Surgery revision due to ineffective stimulation cause by high impedances.	Electrical /Electronic Property Problem
85720	385873	05/05/2023	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Revision surgery due to lead fracture.	Material Integrity Problem
85688	336573	03/03/2023	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	Symptoms developed post device implant. Device removed and symptoms resolved.	Adverse Event Without Identified Device or Use Problem
85598	377339	05/05/2023	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Revision surgery due to ineffective therapy.	Electrical /Electronic Property Problem
85358	396982	16/02/2023	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Abbott Medical Australia Pty Ltd	St Jude Medical	Patient experienced pain at the IPG site.	Patient Device Interaction Problem
84846	336330	27/01/2023	AIMD	Analgesic spinal cord electrical stimulation system pulse generator implantable	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	Explanted due to usage concerns.	Appropriate Term/Code Not Available

84848	400373	11/04/2023	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Boston Scientific Pty Ltd	Boston Scientific Neuromodulation Corporation	Explanted due to patient no longer receiving adequate pain coverage.	Appropriate Term/Code Not Available
84565	396982	10/04/2023	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Abbott Medical Australia Pty Ltd	St Jude Medical	Patient's IPG became unable to communicate with external devices	Communication or Transmission Problem
84442	374776	22/03/2023	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	High low impedances on contacts.	Electrical /Electronic Property Problem
84284	374776	07/02/2023	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Ineffective therapy	Appropriate Term/Code Not Available
84187	374776	22/12/2022	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	The patient elected to have the system explanted.	Electrical/Electronic Property Problem
84185	327091	17/02/2023	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Mainstay Medical Australia Pty Ltd	Mainstay Medical Limited	Patient unable to activate device and receive therapy.	Electrical /Electronic Property Problem
83903	396979	08/04/2023	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Abbott Medical Australia Pty Ltd	St Jude Medical	Revision for unknown reason.	Appropriate Term/Code Not Available
83904	396979	08/04/2023	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Abbott Medical Australia Pty Ltd	St Jude Medical	The patient was unable to connect with the device following a revision procedure.	Communication or Transmission Problem
83874	396982	19/01/2023	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Abbott Medical Australia Pty Ltd	St Jude Medical	The patient's IPG had reached end of life	Appropriate Term/Code Not Available
83875	396979	12/12/2022	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Abbott Medical Australia Pty Ltd	St Jude Medical	Pain.	Appropriate Term/Code Not Available
82700	336330	14/12/2022	AIMD	Analgesic spinal cord electrical stimulation system pulse generator implantable	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	Patient reported having been in hospital for sepsis of unknown origin and renal impairment.	Adverse Event Without Identified Device or Use Problem
83016	374776	24/01/2023	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Ineffective therapy.	Electrical /Electronic Property Problem
82904	374775	23/01/2023	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Infection.	Appropriate Term/Code Not Available
83167	327091	01/12/2022	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Mainstay Medical Australia Pty Ltd	Mainstay Medical Limited	The patient could not feel the stimulation on the Left side.	Adverse Event Without Identified Device or Use Problem
							It was reported that the patient experienced ineffective therapy due to lead migration. X-rays confirmed both leads migrated. As such, surgical intervention took place wherein the leads were explanted and replaced with new leads addressing the issue. Reportedly, therapy was restored post operatively.	
82665	374776	19/01/2023	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical		Patient Device Interaction Problem
82545	374776	18/11/2022	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	The patient's leads is exhibiting high impedances	Electrical /Electronic Property Problem
82324	336330	23/10/2022	AIMD	Analgesic spinal cord electrical stimulation system pulse generator implantable	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	Pain	Appropriate Term/Code Not Available
82557	327091	17/02/2023	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Mainstay Medical Australia Pty Ltd	Mainstay Medical Limited	It was reported that the patient had increasing pain and a suspected infection at the battery site.	Patient Device Interaction Problem
82163	336330	28/10/2022	AIMD	Analgesic spinal cord electrical stimulation system pulse generator implantable	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	Device explanted due to infection.	Patient Device Interaction Problem
82195	374776	12/01/2023	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	It was reported the patient experienced ineffective stimulation.	Output Problem
81843	374776	09/01/2023	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Leads replaced due to ineffective therapy caused by high impedance.	Electrical /Electronic Property Problem
81561	374776	25/01/2023	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Revision surgery as the patient reportedly was not receiving effective therapy.	Electrical /Electronic Property Problem
81526	385873	28/09/2022	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	A dural tear occurred.	Material Integrity Problem
81368	374776	24/08/2022	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Patient was not receiving effective therapy, the lead had high impedances.	Electrical /Electronic Property Problem
80769	374776	06/10/2022	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Top of the lead had punctured the Dura.	Material Integrity Problem
80558	374776	24/08/2022	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	The patient was not receiving effective therapy from their system.	Adverse Event Without Identified Device or Use Problem
80535	374649	03/09/2022	AIMD	Analgesic spinal cord electrical stimulation system pulse generator implantable	Abbott Medical Australia Pty Ltd	Abbott Medical	Revision for IPG repositioning in the pocket.	Patient Device Interaction Problem
80536	374776	12/11/2022	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	The patient experienced ineffective stimulation.	Electrical /Electronic Property Problem
80523	384012	05/08/2022	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Lead exhibited high impedances.	Electrical /Electronic Property Problem
80524	384012	06/09/2022	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	The patient experienced severe pain and numbness. As a result, surgical intervention was undertaken wherein the entire system was explanted to address the issue.	Patient Device Interaction Problem
79981	385873	19/08/2022	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Abbott Medical Australia Pty Ltd	Abbott Medical	It was reported the patient experienced ineffective therapy.	Output Problem
79720	336330	17/06/2022	AIMD	Analgesic spinal cord electrical stimulation system pulse generator implantable	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	The CLS pocket site was a little red, warm and was weeping small amounts of fluid, believed to be a localized infection.	Patient Device Interaction Problem
79679	374776	15/07/2022	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Explant due to ineffective stimulation due to lead migration.	Electrical /Electronic Property Problem
79679	374776	15/07/2022	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Explant due to ineffective stimulation due to lead migration.	Patient Device Interaction Problem
79655	374776	05/10/2022	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Physician could not remove the patient's leads because they had tethered to the subcutaneous tissue.	Electrical /Electronic Property Problem
79655	374776	05/10/2022	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Physician could not remove the patient's leads because they had tethered to the subcutaneous tissue.	Mechanical Problem
79297	373340	01/09/2022	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Wash out due to postoperative infection.	Patient Device Interaction Problem
79044	374776	12/10/2022	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Patient was not receiving effective therapy due to lead high impedances.	Electrical /Electronic Property Problem
78809	327091	18/08/2022	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Mainstay Medical Australia Pty Ltd	Mainstay Medical Limited	It was reported that the patient lead was placed too superficially during surgery and, therefore, could not provide contraction.	Activation, Positioning or Separation Problem
78805	374776	18/06/2022	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Reported experienced dehiscence in a small area at the lead incision site. Additionally, also experienced pain radiating around their thighs and legs.	Patient Device Interaction Problem
78409	374776	13/08/2022	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	During implant, the physician was unable to advance one of the leads into the new implantable pulse generator.	Activation, Positioning or Separation Problem
78054	384012	09/07/2022	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Lead is auto reducing due to high impedances.	Electrical /Electronic Property Problem
77867	374776	15/06/2022	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Ineffective pain relief	Electrical /Electronic Property Problem
77535	374775	30/06/2022	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Sharp pain and loss of therapy.	Appropriate Term/Code Not Available
77535	374775	30/06/2022	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Sharp pain and loss of therapy.	Electrical /Electronic Property Problem
77011	336573	16/03/2022	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	Revision due to limited stimulation.	Output Problem
75934	374776	05/02/2022	Class III	Analgesic spinal cord electrical stimulation system pulse generator implantable	Abbott Medical Australia Pty Ltd	Abbott Medical	It was reported that the patient was not receiving effective therapy from their system.	Output Problem
75101	336330	09/02/2022	AIMD	Analgesic spinal cord electrical stimulation system pulse generator implantable	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	A patient implanted with the Evoke System reported an infection.	Appropriate Term/Code Not Available
74896	336330	09/02/2022	AIMD	Analgesic spinal cord electrical stimulation system pulse generator implantable	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	The patient reported no pain relief from the stimulation.	Electrical /Electronic Property Problem
73964	374776	17/12/2021	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Abbott Medical Australia Pty Ltd	Abbott Medical	Patient experienced Cerebrospinal fluid (CSF) leakage during the implant of left lead and experienced headaches 2 days post implant.	Activation, Positioning or Separation Problem
72936	336330	19/11/2021	AIMD	Analgesic spinal cord electrical stimulation system pulse generator implantable	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	A patient reported he had been admitted to hospital for significant bleeding from the Evoke Closed Loop Stimulator wound.	Appropriate Term/Code Not Available
73133	336330	19/11/2021	AIMD	Analgesic spinal cord electrical stimulation system pulse generator implantable	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	Evoke System was explanted due to inadequate therapy.	Compatibility Problem
73193	336573	22/10/2021	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	Revision due to lead migration.	Patient Device Interaction Problem
73194	336573	22/10/2021	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	Revision due to lead migration of both leads.	Patient Device Interaction Problem
72935	336330	12/11/2021	AIMD	Analgesic spinal cord electrical stimulation system pulse generator implantable	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	A patient experienced ongoing pocket pain and pain at the lead anchors when pressed. The patient requested explant of the Evoke System.	Appropriate Term/Code Not Available
73095	336573	12/11/2021	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	Additional Evoke 12C Percutaneous Lead added due to lack of coverage of the patient's pain.	Activation, Positioning or Separation Problem
72850	336573	08/11/2021	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Saluda Medical Pty Ltd	Saluda Medical Pty Ltd	Lead migration	Mechanical Problem
71366	327091	28/07/2021	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Mainstay Medical Australia Pty Ltd	Mainstay Medical Limited	The tip of the right lead was removed following a previous explant procedure in which the tip had been left behind.	Material Integrity Problem
68427	287157	01/03/2021	AIMD	Implantable lumbar neuromuscular electrical stimulation system lead	KD & A Pty Ltd	Stimwave Technologies Inc	Explant due to infection	Appropriate Term/Code Not Available
65499	233169	17/11/2020	Class IIb	Neural-tissue electrical stimulation lead adaptor	Abbott Medical Australia Pty Ltd	St Jude Medical	Possible allergic reaction, as a lump with bruising developed over the insertion site of the adaptors and lead, with no other symptoms.	Appropriate Term/Code Not Available
65499	233169	17/11/2020	Class IIb	Neural-tissue electrical stimulation lead adaptor	Abbott Medical Australia Pty Ltd	St Jude Medical	Possible allergic reaction, as a lump with bruising developed over the insertion site of the adaptors and lead, with no other symptoms.	Patient Device Interaction Problem
64045	287157	24/03/2021	AIMD	Implantable lumbar neuromuscular electrical stimulation system lead	KD & A Pty Ltd	Stimwave Technologies Inc	The patient reported using his arm to prevent a fall and experiencing a reduction in therapy immediately afterwards.	Patient Device Interaction Problem

63811	233169	15/06/2020	Class IIb	Neural-tissue electrical stimulation lead adaptor	Abbott Medical Australia Pty Ltd	St Jude Medical	It was reported the patient experienced pain at the IPG and adapter implant site. As a result, surgical intervention was undertaken.	Appropriate Term/Code Not Available
63227	287157	12/05/2020	AIMD	Implantable lumbar neuromuscular electrical stimulation system lead	KD & A Pty Ltd	Stimwave Technologies Inc	Patient reported feeling something 'pop' prior to the loss of therapy.	Electrical /Electronic Property Problem
63058	287157	16/04/2020	AIMD	Implantable lumbar neuromuscular electrical stimulation system lead	KD & A Pty Ltd	Stimwave Technologies Inc	Explant of device due to infection	Appropriate Term/Code Not Available
61854	287157	14/05/2020	AIMD	Implantable lumbar neuromuscular electrical stimulation system lead	KD & A Pty Ltd	Stimwave Technologies Inc	Complaint of an infection after patient reported of pain and puss.	Appropriate Term/Code Not Available
60735	214838	27/11/2019	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Medtronic Australasia Pty Ltd	Medtronic Inc	Unable to operate or charge device for 2 years	Electrical /Electronic Property Problem
60735	214838	27/11/2019	Class III	Implantable lumbar neuromuscular electrical stimulation system lead	Medtronic Australasia Pty Ltd	Medtronic Inc	Unable to operate or charge device for 2 years	Patient Device Interaction Problem