Submission to TGA consultation: Proposed reclassification of spinal implantable medical devices

March 2019

Our Credo

We believe our first responsibility is to the patients, doctors and nurses, to mothers and fathers and all others who use our products and services. In meeting their needs everything we do must be of high quality. We must constantly strive to provide value, reduce our costs and maintain reasonable prices. Customers' orders must be serviced promptly and accurately. Our business partners must have an opportunity to make a fair profit.

We are responsible to our employees who work with us throughout the world. We must provide an inclusive work environment where each person must be considered as an individual. We must respect their diversity and dignity and recognize their merit. They must have a sense of security, fulfillment and purpose in their jobs. Compensation must be fair and adequate and working conditions clean, orderly and safe. We must support the health and well-being of our employees and help them fulfill their family and other personal responsibilities. Employees must feel free to make suggestions and complaints. There must be equal opportunity for employment, development and advancement for those qualified. We must provide highly capable leaders and their actions must be just and ethical.

We are responsible to the communities in which we live and work and to the world community as well. We must help people be healthier by supporting better access and care in more places around the world. We must be good citizens–support good works and charities, better health and education, and bear our fair share of taxes. We must maintain in good order the property we are privileged to use, protecting the environment and natural resources.

Our final responsibility is to our stockholders. Business must make a sound profit. We must experiment with new ideas. Research must be carried on, innovative programs developed, investments made for the future and mistakes paid for. New equipment must be purchased, new facilities provided and new products launched. Reserves must be created to provide for adverse times. When we operate according to these principles, the stockholders should realize a fair return.

Comments

On behalf of the Johnson & Johnson Family of Companies (herein referred to as Johnson & Johnson), we appreciate the opportunity to provide comments on the Therapeutic Goods Administration's (TGA) *Consultation: Proposed reclassification of spinal implantable medical devices, February 2019.*

It should be noted that we have contributed to and broadly support the submission made by the Medical Technology Association of Australia (MTAA). Our additional commentary is summarised below.

Overall, Johnson & Johnson supports the proposal to introduce a new classification rule for spinal implantable devices with the intent to align with Regulation (EU) 2017/745 (the EU MDR). We note that final interpretation of the equivalent classification rule prescribed in the EU MDR (Rule 8), is still under consideration so it is critical that any outcome of the TGA's proposal aligns accordingly.

Devices in Scope

The classification of spinal implantable devices should be based on their relative risk and should not be based solely on physical location or proximity to the spinal column.

Johnson & Johnson considers the exempt devices such as screws, wedges, plates and instruments to be representative examples of the three types of components of internal spinal stabilisation constructs and therefore, anticipates classifying devices intended to compose an internal spinal stabilisation construct as Class IIb under the proposed new classification rule.

The multi-component devices used to assemble an internal spinal stabilisation construct can be classified into three categories: bone interfacing components, spacer components and connector components. They allow surgeons to construct an implant system to address an individual patient's anatomic and physiologic requirements. The systems consist of an anchor (such as a pedicle screw), longitudinal members (e.g., plates, rods, and/or plate/rod combinations) and transverse connectors. An interconnection mechanism (e.g., offset connector, nuts, screws, sleeves or bolts) may also be utilised. Spacer components (wedges) occupy the place of removed tissue and abut bone. The anchors or screws form the bone-implant interface, the longitudinal members connect the anchoring members, transverse connectors link the longitudinal members, and the spacer components replace removed tissue or bone, all providing immobilisation and stability to the spine to facilitate fusion and bone healing.

The screw, wedge and plate identified in the last bullet of proposed Rule 8 represent examples of spinal construct components from each of the three categories, as described below in Table 1.

Table 1 Categories of Components in an Internal Spinal Stabilization Construct

Category	Description	Representative Example Identified in Rule 8	Other examples of devices within this category
Bone interfacing component	Interfaces with spinal bone; may penetrate or grip the bone	Screw	Staples, hooks and wire
Spacer component	Occupies the place of removed tissue and abuts bone	Wedge	Intervertebral cages and vertebral body replacement cages
Connector component	Connects two or more components in the construct	Plate	Rods, cross connectors, locking screws and nuts

These constructs are temporary fixation devices which serve a finite purpose until fusion is achieved. This is in contrast, for example, to a spinal disc arthroplasty implant, which is intended to replace a spinal segment and preserve functionality of that segment for an indefinite period. Devices intended for fusion have a different intended use and risk profile from non-fusion devices and should, therefore, reflect different classifications.

The class IIb classification of internal spinal stabilisation constructs is supported by the substantial clinical history of use of these constructs, dating back to the 1950s, and the existence of well-established methodologies to characterise the devices. These include recognised standards for materials, biocompatibility and mechanical performance.

The devices are considered well established technologies. This is supported by their long history of clinical use and the substantial body of evidence available from the literature, establishing these components as state-of-the-art treatment for various spinal conditions, including spinal deformity, degenerative disc disease, fracture and tumor. Clinical performance that may impact the benefit-risk ratio have been well studied in published literature covering the lifetime of the target devices and is enough to assess the benefits and risks associated with the devices and to conclude that the benefit-risk profile is acceptable. No new or emerging risks have been identified in the clinical literature or post market surveillance. Manufacturer compliance with well-established standards regarding materials, biocompatibility, mechanical performance and labeling further serve as controls to assure the continued safety and performance of these devices.

The EU Approach

Industry, through trade associations such as MedTech Europe, has been in dialogue with the EU Notified Bodies regarding the appropriate classification of spinal implantable devices over the past two years and developed the attached industry position paper to address the proposed classification of various types of spinal devices. This effort has culminated in Team NB and NB-MED issuing a Joint Position Paper in December of 2018 on Spinal Device Classification per the MDR[1]. This position paper summarises their opinion on Rule 8 of the EU MDR. It was created to facilitate the discussion about the classification of implantable devices and long-term surgical invasive devices as described in the regulation and to ensure a harmonised implementation of the classification rules throughout Notified Bodies. It aims to provide a risk-based decision tree which considers the establishment level of the various devices, their clinical evidence and the risks associated with their usage. Pages 3-4 of the document describe a proposed approach to the classification of spinal implants- specifically, retaining a class IIb classification for spinal systems indicated for fusion and class III for non-fusion systems (i.e., dynamic). The Class IIb systems are further differentiated by considerations for well-established technologies (WET) and non-WET devices.

Given the TGA's intent to align with the EU MDR and the approach outlined in the Team NB and NB-MED joint position paper, we urge the TGA to adopt a similar risk-based approach to promote harmonisation of the classification of spinal implantable devices in Australia and the EU.

The FDA Approach

There have been several reclassification efforts in the United States for spinal devices, including FDA officially reclassifying pedicle screw systems when used as an adjunct to spinal fusion procedures from class III to class II, reclassifying intervertebral body fusion devices (cages) from class III to class II, and proposed classification of posterior cervical pedicle screws systems (previously unclassified) as class II devices.

In 2007, FDA reclassified intervertebral body fusion devices from Class III to Class II based on their well-characterised safety and effectiveness profile. Likewise, on December 30, 2016, FDA officially reclassified pedicle screw systems when used as an adjunct to spinal fusion procedures from class III, pre-amendment, to class II. Similarly, classification efforts are underway in the US for previously unclassified posterior cervical spinal systems, with FDA publishing a proposed classification rule in March of 2016 to classify these systems as Class II devices, subject to special controls (final classification rule is pending publication).

Each of these reclassification efforts was based on an analysis of substantial clinical evidence (both safety and effectiveness) and the establishment of special controls (such as materials, testing and labeling) to mitigate risks. We urge the TGA to consider a similar risk-based approach that is informed

[1] Joint NB-Position Paper on Spinal Classification per the MDR, 07-12-2018: http://www.team-nb.org/wp-content/uploads/2019/01/Joint-NB-Spinal-Classification-Decision-Tree_final.pdf

by substantial existing data. Additional requirements for conformity assessment would be unlikely to yield new information or to identify unknown risks of implantable spinal devices and would be likely to delay or deny patient access to important spinal treatment technologies.

This approach is also consistent with the spirit of harmonisation and the principles outlined in the TGA's previous consultation on direct recognition of reviews from other IMDRF regulators, such as the FDA.

Transitional arrangements

The TGA transition should be scheduled to end at least 6 months after the end of the European transition arrangements (May 2024) to allow adequate time for applicants to finalise European certification prior to lodging applications to include the device in the ARTG.

Johnson & Johnson appreciates the ongoing engagement and opportunity for input to the TGA's proposal to reclassify spinal implantable medical devices. Should you have any questions regarding our consultation feedback, we welcome the opportunity to discuss further.

Examples of spinal device product categories classification under the EU Medical Devices Regulations (EU) 2017/745

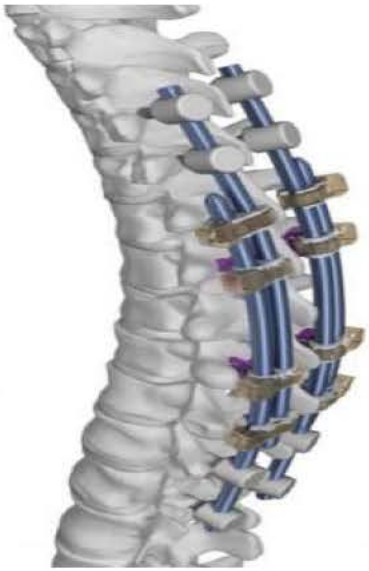
January 2018

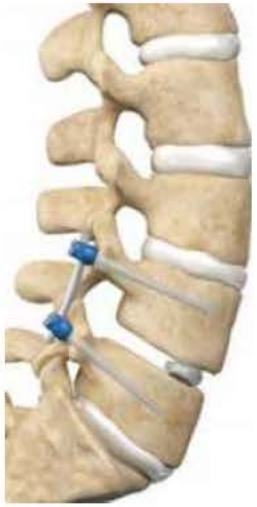
The Medical Device Regulations (2017/745) published by the European Commission, replaced the Medical Devices Directive (93/42/EEC) and modified the classification of spinal devices outlined in Rule 8 of Annex VIII. MDR Annex VIII Rule 8 specifies that *All implantable devices and long-term surgically invasive devices are classified as class IIb unless they*: *are spinal disc replacement implants or are implantable devices that come into contact with the spinal column, in which case they are classified as class III with the exception of components such as screws, wedges, plates and instruments.*

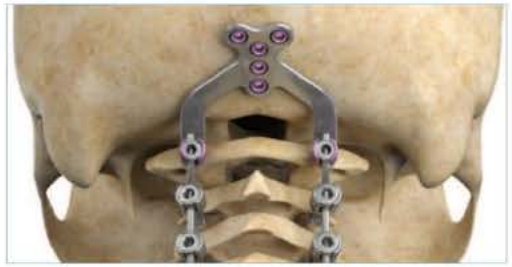
Industry interprets screws, wedges and plates (i.e., Well Established Technology or WET) as representative examples of the three types of components of common internal spinal stabilization constructs and has employed a risk-based approach to the classification of typical categories of spinal devices.

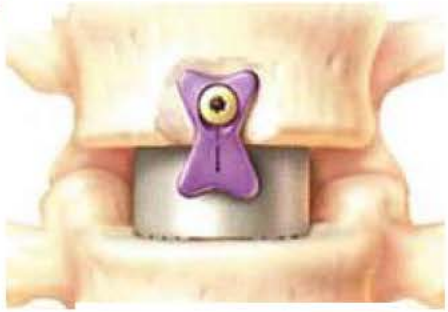
Subject: Industry Position Examples of spinal device product categories classification

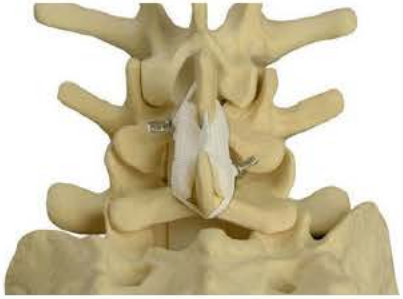
Product Category	MDR Classification / Rationale	Examples
Cervical and Lumbar Total Disc Replacement Devices (motion preserving devices)	Class III • Intended to replace an intervertebral disc and restore disc height and segmental motion • Spinal disc replacement implants	 **Mobi-C (Zimmer Biomet)**  **Prodisc-L (DePuy Synthes)**

Product Category	MDR Classification / Rationale	Examples
Pedicle Screw/Rod and Pediatric Growing Rod Systems (non-fusion devices)	Class IIb (WET) • Screws covered under WET screw exception • Intended for stabilization of segmental motion or deformity correction of pediatric scoliotic spine while allowing for constrained motion or linear growth, without additional surgery for rod lengthening. • Some components do not contact spinal column (i.e., rods and connectors)	 **TROLLEY (DePuy Synthes)**  **PERFX-2 (Eden Spine)**  **MAGEC (NuVasive)**

Product Category	MDR Classification / Rationale	Examples
Cervical and non-cervical Screw (pedicle and non-pedicle) Hook/Rod/ Connector Systems	Class IIb (WET) • Covered under WET screw exception • Fenestrated/Perforated screws also covered under WET screw exception • Intended to provide segmental stabilization of the spine to promote fusion • Some components do not contact spinal column (i.e., rods and connectors) • Pedicle screw/hook/rod systems have extensive clinical history with a well-understood risk profile. The devices are intended to function as an adjunct to fusion; they stabilize the spine while fusion is occurring (approximately 6-12 months). Once fusion occurs, the intended purpose of stabilization and load-bearing functions are achieved.	 **Synapse and Expedium (DePuy Synthes)**  **Xia 4.5 Evolution (Stryker)** **PEEK rods** 

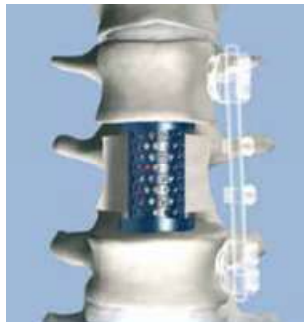
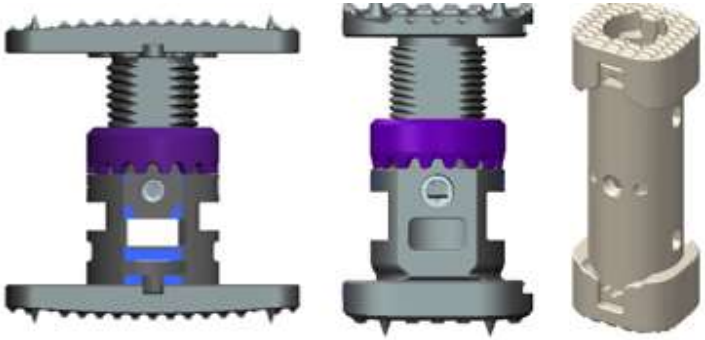
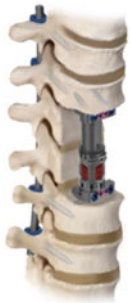
Product Category	MDR Classification / Rationale	Examples
Occipito-Cervical and Cervical Spinal Plates	Class IIb (WET) • Covered under WET plate exception • Intended to provide stabilization of the occipito-cervical junction and cervical spine to promote fusion • Spinal plate & screw systems have extensive clinical history with a well-understood risk profile. The devices are intended to function as an adjunct to fusion; they stabilize the spine while fusion is occurring (approximately 6-12 months). Once fusion occurs, the intended purpose of stabilization and load-bearing functions are achieved.	 **OASYS System (Stryker)**  **Zevo Cervical Plate (Medtronic)**  **Archon Anterior Cervical Plate (NuVasive)**  **Helix Revolution (NuVasive)**

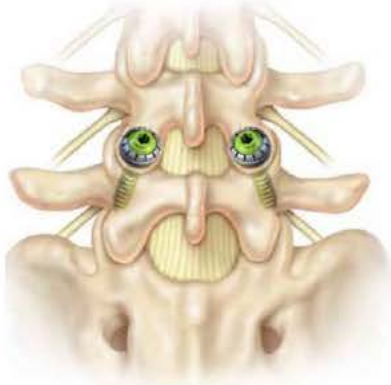
Product Category	MDR Classification / Rationale	Examples
Thoracolumbar and Lumbosacral Spinal and Buttress Plates	Class IIb (WET) • Covered under WET plate exception • Intended to provide stabilization of the thoracolumbar and lumbosacral spine to promote fusion • Intended to stabilize and buttress bone graft as an aid to spinal fusion • Spinal plate & screw systems have extensive clinical history with a well-understood risk profile. The devices are intended to function as an adjunct to fusion; they stabilize the spine while fusion is occurring (approximately 6-12 months). Once fusion occurs, the intended purpose of stabilization and load-bearing functions are achieved.	 **LITe Plate System (Stryker)**  **BowTi Buttress (DePuy Synthes)**  **Halo ALIF Buttress Plate NuVasive)**

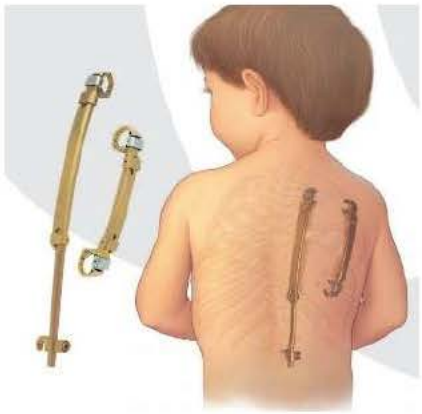
Product Category	MDR Classification / Rationale	Examples
Interspinous Spacers/Plates	Class IIb (WET) • Covered under WET wedge and plate exceptions • Intended for use as a space holder between the spinous processes in the non-cervical spine (T1-S1). • Controls the segmental extension and distracts the interspinous space • Functions as a wedge or plate	 **STENOFIX (DePuy Synthes)**  **AILERON (Life Spine)**  **DIAM (Medtronic)**

Product Category	MDR Classification / Rationale	Examples
Cervical and Thoracolumbar Interbody Cages	Class IIb (WET) • Covered under WET wedge exception • For devices which incorporate screws and/or anchors, also covered under WET screw exception • Used to secure spacing between the vertebral bodies during the time it takes fusion to be achieved but do not replace the function of a natural disc • Expandable devices function as static devices once locked in place in situ and are therefore also covered by WET wedge exception • Interbody spacers/cages have extensive clinical history and a well-understood risk profile. These devices function as a wedge to maintain spacing and curvature between two vertebral bodies while fusion occurs (intended for use as adjunct to fusion). Once fusion occurs after approximately 6-12 months, the intended purpose is achieved. The bony fusion maintains the vertebral body spacing and curvature and provides the load support.	 **SYNFIX Evolution (DePuy Synthes)**  **pezo-P (Ulrich Medical)**  **Aero-C (Stryker)**

Product Category	MDR Classification / Rationale	Examples
Cervical and Thoracolumbar Interbody Cages (pre-filled with Class III graft material)	Class III • Used to secure spacing between the vertebral bodies during the time it takes fusion to be achieved but do not replace the function of a natural disc • Filled with resorbable graft material, thus up-classifying the wedge from Class IIb to III • Resorbable graft materials may vary in terms of risk profile and materials.	 **Cervios chronOS (DePuy Synthes)**

Vertebral Body Replacement (VBR) Devices	Class IIb (WET) • Covered under WET wedge exception • Expandable devices function as static devices once locked in place in situ and are therefore also covered by WET wedge exception • <u>Rationale:</u> VBR devices have a well-understood risk profile and have extensive clinical history. These devices function as a wedge to maintain vertebral body spacing and curvature while fusion is occurring (intended for use as adjunct to fusion). • Once fusion occurs after approximately 6-12 months, the intended purpose is achieved. The bony fusion maintains the vertebral body spacing and curvature and provides the load support.	 **X-MESH (DePuy Synthes)**  **VBOSS (Strvker)**  **X-Core Expandable VBR System, X-Core Mini Cervical Expandable VBR System, Monolith Corpectomy System (NuVasive)**   **FORTIFY®(Globus)**

Product Category	MDR Classification/ Rationale	Examples
Facet Screws	Class IIb (WET) • Covered under WET screw exception • Spinal facet screws have a well-understood risk profile and extensive clinical history. These devices are intended to immobilize and stabilize the facet joint, serving as an adjunct to fusion. Spinal facet screws function purely as screws, securing two sides of a joint together.	 **Viper F2 (DePuy Synthes)**
Facet Wedges	Class: IIb (WET) • Covered under WET wedge and screw exception • Similar to facet screws and cages	 **Facet Wedge (DePuy Synthes)**

Product Category	MDR Classification / Rationale	Examples
Vertical Expandable Prosthetic Titanium Rib	Class IIb (WET) • Covered by WET screw exception Intended to stabilize and distract the thorax to improve respiration and lung growth and are expanded at regular intervals through surgery • Construct locked into place and therefore functions as a screw/hook/rod construct • Some components do not contact spinal column (i.e., rods)	 **VEPTR (DePuy Synthes)**
Vetebral Body Stents	Class: III • Intended to create a void in the spine and/or for reduction of vertebral compression fractures • Not covered under exceptions	 **VBS (DePuy Synthes)**