



12 March 2019

Priyanka Rai  
Policy Manager  
Painaustralia  
PO Box 9406  
Deakin ACT 2600  
E: priyanka.raai@painaustralia.org.au

Dear Priyanka

Thank you very much for the opportunity to provide feedback on the proposed reclassification of spinal implantable medical devices towards Painaustralia's submission to the Australian Government Department of Health, Therapeutic Goods Administration (TGA).

NSANZ believes that the proposed reclassification of spinal implantable medical devices appears practical, sensible and reasonable.

*Spinal cord stimulator systems, peripheral nerve stimulator systems and pain pumps* do not form part of these spinal implantable devices under review i.e. spinal disc replacement implants or any implantable devices that come into contact with the spinal column, for the following reasons:

- a. Spinal cord stimulator systems, peripheral nerve stimulator systems and pain pumps are not used in any way to treat *spinal pathologies* or physical/structural abnormalities of the spine or spinal column.
- b. Spinal cord stimulator systems, peripheral nerve stimulator systems and pain pumps do not alter the spine or spinal column in anyway.
- c. Spinal cord stimulator systems, peripheral nerve stimulator systems and pain pumps are not implanted into the spine, nor do they come into contact with the spinal column.
- d. Spinal cord stimulator systems, peripheral nerve stimulator systems and pain pumps should be used to treat medical and physiological conditions (i.e. non-structural conditions) like chronic refractory pain only and other conditions like spasticity.

In conclusion, the devices referred to in this submission - namely Spinal cord stimulator systems, peripheral nerve stimulator systems and pain pumps should remain under their

current classification level as set out in Schedule 2, Part 3 of the Therapeutic Goods (Medical Devices) Regulations 2002.

Again, the Neuromodulation Society of Australia and New Zealand (NSANZ) thanks you for the opportunity to contribute. If you require any further input, we'd be happy to do so.

Yours sincerely,



Dr Richard Sullivan  
President  
Neuromodulation Society of Australia and New Zealand (NSANZ)

On behalf of NSANZ Board:

Dr Nick Christelis  
Dr Murray Taverner  
Dr Paul Verrills  
Dr Marc Russo  
Dr Frank Thomas  
Dr James Yu  
DR Philip Finch

CC.  
Therapeutic Goods Administration  
PO Box 100  
Woden ACT 2606  
[devicereforms@tga.gov.au](mailto:devicereforms@tga.gov.au).