NEUROMED

K960728

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510(k) Summary of Safety and Effectiveness

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

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Implanted Spinal Cord Stimulator Lead
510(k) Summary of Safety and Effectiveness

Device Information:

Trade Names:	Quattrode Plus™ One Step Connect™ Lead
	Octrode Plus™ One Step Connect™ Lead
	Cervitrode Plus™ One Step Connect™ Lead
Common Name:	Spinal Cord Stimulator
Classification Name:	Implanted Spinal Cord Stimulator for Pain Relief

Predicate Device:

Neuromed, Inc., currently markets spinal cord stimulator systems with polyethylene lead insulators under 510(k) # K810182A and K860158A.

Device Description:

Neuromed, Inc.'s One-Step Connect™ Leads are implantable devices consisting of spaced electrodes connected by wires within a cover sheath. These percutaneous leads are introduced into the epidural space superior to the spinal segment responsible for pain impulse transmission, and connected to a radio-frequency (RF) receiver or pulse generator.

Intended Use:

Neuromed, Inc.'s One-Step Connect™ Leads are intended to be used with Neuromed trial extensions and/or receivers, transmitters, and antennae to electrically stimulate spinal cord fiber tracts for treatment of chronic pain of the extremities and/or trunk. The proposed device modification does not affect the original intended use of the legally marketed device.

Comparison To Predicate Device:

The following table illustrates the comparison between the modified device and the original, legally marketed device.

	Predicate Device 510(k) K810182A, K860158A	**Modified Device**
Intended Use:	Stimulation of spinal cord for treatment of chronic pain	Stimulation of spinal cord for treatment of chronic pain
Materials:		
• **Electrode:**	Platinum/Iridium	Platinum/Iridium
• **Contact Terminal:**	Stainless Steel 304	Stainless Steel 304
• **Insulator:**	Polyethylene	Polyurethane
Design Features:	Multi-electrode	Multi-electrode

	Catheter Braided Wire Cable Platinum/Iridium Electrode 4 or 8 Stainless Steel Contact Terminals Percutaneous Introduction	Catheter Braided Wire Cable Platinum/Iridium Electrode 4, 7, or 8 Stainless Steel Contact Terminals Percutaneous Introduction
Dimensions: • **Length:** • **Catheter Size:**	66 cm 4 Fr.	58 - 66 cm 4 Fr
Packaging:	Tray w/ Tyvek Lid	Tray w/ Tyvek Lid
Labeling:	Labeled as sterile, prescription device	Labeled as sterile, prescription device

Non-clinical Testing:

Biostability testing of the polyurethane material using the Stokes method is provided in the manufacturer's Master File.

Comparative testing of product fatigue strength indicates that the polyurethane lead insulators have equivalent or better durability than the original polyethylene insulators.

Comparative tensile strength testing of the original polyethylene lead insulators and the proposed new polyurethane lead insulators demonstrates an equivalent or better bond strength between the polyurethane insulator material and the electrodes.

Master File biocompatibility information, combined with supplemental testing performed by Neuromed, Inc., demonstrates that the change from polyethylene to polyurethane raises no significant safety or effectiveness questions relating to biocompatibility.