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k990469

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.

Date Prepared:	February 1, 1999
Company:	Advanced Neuromodulation Systems, Inc. One Allentown Parkway Allen, TX 75002-4211
Contact:	Drew Johnson
Phone Number:	972-390-9800 Ext. 327
Fax Number:	972-390-2881

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

Device Information:

Trade Names:	Lamitrode® Model 1916L Lead
	Lamitrode® Model 1944L Lead
	Lamitrode® Model 1992LS Lead
	Lamitrode® Model 1995L Lead
	Lamitrode® Model 1998L Lead
Common Name:	Spinal Cord Stimulator
Classification Name:	Implanted Spinal Cord Stimulator for Pain Relief

Predicate Device:

Advanced Neuromodulation Systems, Inc.,., currently markets spinal cord stimulator systems with Silicone lead insulators under 510(k) # K853643 and K905255 and K960728.

Device Description:

Advanced Neuromodulation Systems, Inc.'s Lamitrode Leads are implantable devices consisting of spaced electrodes connected by wires within a cover sheath. These lamitrode leads are introduced into the epidural space via a hemilaminectomy, superior to the spinal segment responsible for pain impulse transmission, and connected to a radio-frequency (RF) receiver or pulse generator.

Intended Use:

Advanced Neuromodulation Systems, Inc.'s Lamitrode Leads are intended to be used with Advanced Neuromodulation Systems 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, the original legally marketed device and other legally marketed devices.

	ANS Predicate Device 510(k) K853643, K905255, K960728	Medtronic Predicate Device 510(k) K884948, K811655, and K905407	ANS Modified Device K# Under Review
Intended Use:	Stimulation of spinal cord for treatment of chronic pain of the trunk and limbs	Stimulation of spinal cord for the treatment of chronic pain of the trunk and limbs	Stimulation of spinal cord for treatment of chronic pain of the trunk and limbs
Materials: • **Electrode:** • **Contact Terminal:** • ***Insulator:***	Platinum/Iridium Stainless Steel 304 Silicone (K960728) Polyurethane	Same Silicone Polyurethane	Platinum/Iridium Stainless Steel 304 Polyurethane
Design Features:	***Multi-electrode Catheter*** Braided Wire Cable Platinum/Iridium Electrode 4,8,or 16 electrodes Laminectomy Introduction Percutaneous Introduction (K960728)	 Platinum/Iridium Electrode 4 and 8 staggered electrodes Laminectomy Introduction	***Multi-electrode Catheter*** Braided Wire Cable Platinum/Iridium Electrode 4,8, or 16 electrodes Laminectomy Introduction
Dimensions: • **Length:**	58 - 80 cm	10 - 100 CM	58 - 80 cm
Packaging:	Tray w/ Tyvek Lid	Tray w/ Tyvek Lid	Tray w/ Tyvek Lid
Labeling:	Labeled as sterile, prescription device	Labeled as sterile, prescription device	Labeled as sterile, prescription device

Non-clinical Testing:

Biostability testing of the polyuethane and silicone material is provided in the manufacturer's Master File. Master File biocompatibility information demonstrates that the change to polyurethane and platinum cured silicone raises no significant safety or effectiveness questions relating to biocompatibility.

Comparative testing of product bond strength indicates that the polyurethane lead insulator to the platinum cured paddle has a better bond strength than the current product.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 3 1999

Mr. Drew Johnson
Director, Regulatory Affairs
Advanced Neuromodulation Systems, Inc.
One Allentown Parkway
Allen, Texas 75002-4211

Re: K990469
Trade Name: Lamitrode Spinal Cord Stimulation Leads, Lamitrode® 1916L, 1944L, 1992LS, 1995L, and 1998L
Regulatory Class: II
Product Code: GZB
Dated: May 17, 1999
Received: May 18, 1999

Dear Mr. Johnson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K990469

Device Name: Lamitrode Spinal Cord Stimulation Lead

Indications For Use:

Advanced Neuromodulation Systems Lamitrode Spinal Cord Stimulation Leads are indicated for the treatment of chronic pain of the trunk and limbs, either as the sole mitigating agent, or as an adjunct to other modes of therapy used in a multidisciplinary approach and is intended to be used with Advanced Neuromodulation Systems extensions and/or receivers, transmitters, and antennae. The proposed device modification does not affect the original intended use of the legally marketed device.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K990469

Prescription Use X
(Per 21 CFR 801.109)