JUN 24 1999

ANS

K991784

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: May 21, 1999

Company: Advanced Neuromodulation Systems, Inc.
One Allentown Parkway
Allen, TX 75002-4211

Contact: Katryna Warren
Phone Number: 972-390-9800 Ext. 332 or
972-309-8000
Fax Number: 972-390-2881 or (972) 309-8150

ANS

K991784

Lead Extension
510(k) Summary of Safety and Effectiveness

Device Information:

Trade Names: Renew Lead Extension Model 3382
Renew Lead Extension Model 3383
Renew Dual Lead Extension Model 3341
Renew Dual Lead Extension Model 3342
Renew Dual Lead Extension Model 3343

Common Name: Spinal Cord Stimulator

Classification Name: Implanted Spinal Cord Stimulator for Pain Relief

Predicate Device:

Advanced Neuromodulation Systems, Inc., currently markets One Step Connect™ Leads under 510(k) # K960728 and Octrode Neurostim Receiver under 510(k) # K930536.

Device Description:

The Renew Lead Extension consists of a silicone connector body, with Platinum/Iridium contacts, and braided wire cable inside a polyurethane sheath. Lead extensions are designed to be implanted to add additional length to the lead for connection to a receiver or externalized for use during a trial stimulation period not to exceed 30 days.

Intended Use:

ANS Renew Lead Extensions 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. Lead extensions are intended to be used with Advanced Neuromodulation Systems, leads, receivers, transmitters, and antennae.

Comparison To Predicate Device:

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

	ANS Predicate **Device 510(k)** K960728, K930536	**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 treatment of chronic pain of the trunk and limbs
Materials: • **Electrode:** • **Contact Terminal:** • ***Insulator:*** • ***Connector Coating***	 Platinum/Iridium Stainless Steel 304 Polyurethane Silicone (K930536)	 N/A Platinum/Iridium Polyurethane Silicone
Design Features:	Braided Wire Cable 4,8,or 16 electrodes Percutaneous Introduction	Braided Wire Cable N/A – The extension connects with the terminal end of the lead Percutaneous Introduction/ External Use
Dimensions: • **Length:**	 58 - 80 cm	 10 - 30 cm
Sterilization	100% ETO Sterility Assurance Level (SAL) 1x 10^{-6}	100% ETO Sterility Assurance Level (SAL) 1x 10^{-6}
Packaging:	Tray w/ Tyvek Lid	Tray w/ Tyvek Lid
Labeling:	Labeled as sterile, prescription device	Labeled as sterile, prescription device

Non-clinical Testing:

The biocompatible materials used to construct the lead extension are the same type as those used for predicate devices with the same classification regulation, for the same intended use. The addition of this extension raises no significant safety or effectiveness questions.

Verification testing was performed as required by the risk analysis for this modification. The results demonstrated that the acceptance criteria were met for the following tests: Insulation Resistance, Conductor Resistance System Impedance, Dielectric Strength, Accelerated Contact Resistance, Connector Pull Test, Lead Body Flex Life, Strain Relief Flex Life, Stiffness, and Setscrew Block Retention.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 24 1999

Ms. Katryna Warren
Advanced Neuromodulation Systems
One Allentown Parkway
Allen, Texas 75002-4211

Re: K991784
Trade Name: Renew ™ Lead Extension
Regulatory Class: II
Product Code: GZB
Dated: May 21, 1999
Received: May 25, 1999

Dear Ms. Warren:

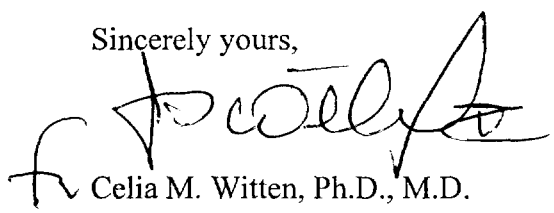
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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,



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

510(k) Number (if known): K991784

Device Name: Lead Extension

Indications For Use:

ANS Lead Extensions 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. Lead extensions are intended to be used with Advanced Neuromodulation Systems', leads, receivers, transmitters, and antennae.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use ___
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K991784