

SEP 24 1999



K992946

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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.

Date Prepared: August 16, 1999

Company: Advanced Neuromodulation Systems, Inc.
6501 Windcrest, Suite 100
Plano, Texas 75024

Contact: Katryna Warren
Phone: 972-309-8000 ext. 8109
Fax Number: 972-309-8150

Renew Receiver
510(k) Summary of Safety and Effectiveness

Device Information:

Trade Names: *Renew Receiver Model 3408*
Renew Receiver Model 3416

Common Name: Spinal Cord Stimulator

Classification Name: Implanted Spinal Cord Stimulator for Pain Relief

Predicate Device:

Advanced Neuromodulation Systems, Inc., currently markets Octrode Neurostim Receiver under 510(k) # K930536 and Renew Lead Extension under 510(k) # K991784.

Device Description:

Renew Receiver contains electronic circuitry that decodes and converts programming data into stimulation pulses. The circuitry is hermetically and encapsulated in epoxy. The lead connection adapter, header, on the receiver is covered and sealed with biocompatible silicone rubber.

Intended Use:

ANS *Renew* Receivers 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. Receivers are intended to be used with Advanced Neuromodulation System', leads, extensions, transmitters and antennae.

Comparison To Predicate device:

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

	ANS Predicate Device 510(k) K930536, K991784	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:		
• Connector Coating:	Silicone, 40076 (K991784) Silicone (K930536)	40076
• Contact Terminal:	Platinum/Iridium (K991784)	Platinum/Iridium
• Connector Header	Silicone	Silicone
Design Features:	4, 8, and 16 Channel (K930536) Percutaneous Introduction (K930536)	4,8, and 16 Channel Percutaneous Introduction
Dimensions:	1.75" x .43"	35mm(1.4") x 11mm (0.414")
Sterilization:	100% ETO Sterility Assurance Level (SAL) 1×10^{-6}	100% ETO Sterility Assurance Level (SAL) 1×10^{-6}
Packaging:	Tray w/ Tyvek Lid	Tray w/ Tyvek Lid
Labeling:	Labeled as sterile, prescription device	Labeled as sterile, prescription device

Non-clinical Testing:

Biocompatibility testing of the material is provided in the manufacturer's Master file. Verification testing was performed as required by the risk analysis for this modification. The results demonstrated that the acceptance criteria were met for Impedance testing.

Master file biocompatibility information combined with verification testing performed by Advanced Neuromodulation Systems, Inc. demonstrates that the change raises no significant safety or effectiveness questions.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Katryna Warren
Senior Regulatory Specialist
Advanced Neuromodulation Systems, Inc.
6501 Windcrest Drive, Suite 100
Plano, Texas 75024

Re: K992946
Trade Name: Renew Receiver
Regulatory Class: II
Product Code: GZB
Dated: August 31, 1999
Received: September 1, 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.

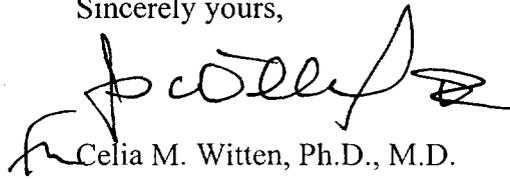
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

Page 2 – Ms. Katryna Warren

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) 594-4595. 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,

A handwritten signature in black ink, appearing to read 'C. Witten', is written over the typed name.

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):

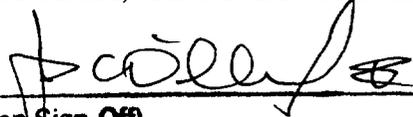
Device Name: *Renew Receiver*

Indications For Use:

ANS *Renew* Receivers 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. Receivers are intended to be used with Advanced Neuromodulation System', leads, extensions, transmitters and antennae.

(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

K992946

Prescription Use
(Per 21 CFR 801/109)

Or

Over-The-Counter Use

000004