



APR 24 2003

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Rashmi Moza
Regulatory Affairs Specialist
Advanced Neuromodulation Systems, Inc.
6501 Windcrest Drive, Suite 100
Plano, Texas 75024

Re: K030461

Trade/Device Name: A127 Lead Extension Models 2341, 2342, 2343 and 2346
Regulation Number: 21 CFR 882.5880
Regulation Name: Implanted Spinal Cord Stimulator for Pain Relief
Regulatory Class: Class II
Product Code: GZB
Dated: February 11, 2003
Received: February 12, 2003

Dear Ms. Moza:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

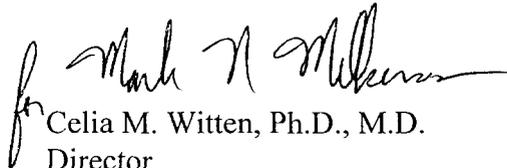
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

Page 2 – Ms. Rashmi Moza

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 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 21 CFR Part 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten". The signature is written in a cursive style with a large initial "C".

Celia M. Witten, Ph.D., M.D.
Director

Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number:

Device Name: A127 Lead Extension

Indications for Use:

The ANS® A127 Lead Extension is designed to be utilized as the lead extension component of a spinal cord stimulation system (SCS) and is indicated for spinal cord stimulation in the treatment of chronic pain of trunk and limbs, either as the sole mitigating agent, or as an adjunct to other modes of therapy used in a multidisciplinary approach.

The A127 Lead Extension Models 2341, 2342, 2343 and 2346 are designed to be used with the following devices:

- Micronet Axxess™ Lead Model 8000, 8100 and 8200 series
- Medtronic Pisces Quad® Lead Model 3487
- Medtronic Pisces Quad® Plus Lead Model 3888
- Medtronic Pisces Quad® Compact Lead Model 3887
- Medtronic Specify™ Lead Model 3998
- Medtronic Resume® II Lead Model 3587A
- ANS Renew® Receiver Model 3408
- ANS Renew® Transmitter Model 3508

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Or Over-The-Counter Use

for Mark A. Mulken
 (Division Sign-Off)
 Division of General Restorative
 and Neurological Devices

510(k) Number K030461