DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 12 2006

Amy Clendening
Regulatory Affairs Specialist
Advanced Neuromodulation Systems
6901 Preston Road
Plano, Texas 75024

Re: K063080
Trade/Device Name: Lamitrode Series Leads:
- Tripole 8C (model numbers 3209, 3210, 3211, and 3212),
- Tripole 16C (model numbers 3213, 3214, 3215, and 3217), and
- Exclaim 8 (model numbers 3223, 3224, 3225, and 3226)

Regulation Number: 21 CFR 882.5880
Regulation Name: Implanted spinal cord stimulator for pain relief
Regulatory Class: Class II
Product Code: GZB
Dated: November 20, 2006
Received: November 21, 2006

Dear Ms. Clendening:

We have reviewed your Section 510(k) premarket notification of intent to market the devices referenced above and have determined the devices are 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 devices, 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 devices are 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 devices can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your devices in the Federal Register.

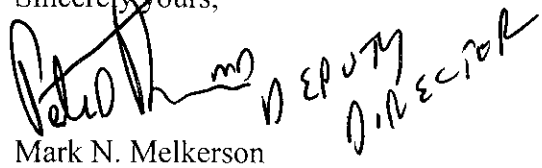
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your devices comply with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

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 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 devices as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to a legally marketed predicate device results in a classification for your devices and thus, permits your devices to proceed to the market.

If you desire specific advice for your devices on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



For Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K063080

Device Name: ANS Tripole 8C, Tripole 16C, and Exclaim 8 Lamitrode Lead Kits

Indications For Use:

Advanced Neuromodulation Systems Tripole 8C, Tripole 16C, and Exclaim 8 Lead Kits are indicated for the management 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 are intended to be used with Advanced Neuromodulation Systems receivers, transmitters, and/or antennae.

Prescription Use _X_ Or Over-The-Counter Use __
(Per 21 CFR 801.109)

(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, and Neurological Devices

510(k) Number K063080