



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAR 28 2003

Drew Johnson  
Vice President Regulatory and Clinical Affairs  
Advanced Neuromodulation Systems, Inc.  
6501 Windcrest Drive, Suite 100  
Plano, Texas 75024

Re: K030674

Trade/Device Name: Axxess Spinal Cord Stimulation Lead  
Regulation Number: 21 CFR 882.5880  
Regulation Name: Implanted Spinal Cord Stimulator for Pain Relief  
Regulatory Class: Class II  
Product Code: GZB  
Dated: February 21, 2003  
Received: March 4, 2003

Dear Mr. Johnson:

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.

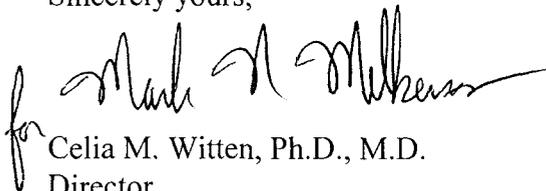
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's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

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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 long horizontal flourish extending to the right.

for 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

**Indications for Use Page**

510(k) Number (if known):           K030674          

Device Name: **Axxess Spinal Cord Stimulation Lead, Model 8000 Series**

Indications for Use: The AXXESS™ Lead is designed to be utilized as the lead component of a spinal cord stimulation system and is used to aid in the management of chronic pain of the trunk and/or extremities.

The AXXESS™ lead system is designed to be used with the following devices:

- Medtronic® Matrix® Model 3272 RF system receiver and compatible transmitter, or
- Medtronic® X-TREL® Model 3470 RF system receiver and compatible transmitter using the Medtronic® Model 7495 Quadripolar extension , and
- Medtronic® Model 3550-05 Percutaneous Extension with the Medtronic® Model 3550-03 Screener cable, and
- The Medtronic® Model 3628 DualScreen™ Screener using Axxess Screener Cable or
- The ANS TS-8 or MNT90T/TR-16 Test Stimulator using Axxess Screener Cable.

*for*           Mark A. Milken            
(Division Sign-Off)  
Division of General, Restorative  
and neurological Devices

510(k) Number           K030674          

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use   ✓    
(Per 21 CFR 801.109)

Or

Over-the-Counter Use