DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Advanced Neuromodulation Systems
c/o Ms. Penny Houston, MBA, MHL
Regulatory Affairs Specialist
6901 Preston Road
Plano, TX 75024

DEC 23 2009

Re: K092371
Trade/Device Name: Swift-Lock™ Anchor (Model 1192)
Regulation Number: 21 CFR 882.5880
Regulation Name: Implanted Spinal Cord Stimulator for Pain Relief
Regulatory Class: II
Product Code: GZB
Dated: December 9, 2009
Received: December 10, 2009

Dear Ms. Houston:

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 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

3. Statement for Indications for Use

Indications for Use Statement

510(k) Number (if known): K092371

Device Name: **Swift-Lock™ Anchor**

Indications for Use:

ANS Neurostimulation Systems are indicated for spinal cord stimulation (SCS) in 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.

The Swift-Lock™ anchor is intended to be an accessory to the leads component of ANS SCS systems functioning to secure the lead to the fascia or inter-spinous/supra-spinous ligament.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Jeffrey Toy

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K092371