K072736

5. 510(k) Summary

510(k) Summary of Safety and Effectiveness

Company Name:

Rhythmlink International, LLC
1256 First Street South Extension
Columbia, SC 29209

JAN 22 2008

Phone: 803-252-1222
FDA Registration #: 1067162

Official Contact Person:

James M. Mewborne, Engineering and Regulatory Manager

Summary Date:

September 21, 2007

Device Identification:

Proprietary Device Name:
Rhythmlink International Monopolar Stimulating Instrument (Trade names have not been finalized at this time)

Generic Device Name:
Nerve Stimulator/Locator

Regulatory Class: Class II
Classification Name: 21 CFR 874.1820, Surgical nerve stimulator/locator

This device has not been previously submitted to the FDA.

Predicate Device(s):

510(k) Number: K031003
Manufacturer: Medtronic Xomed
Trade Name: Stimulation/Dissection Instruments
Product Code: 874.1820

Device Description:

The design of the Rhythmlink International Monopolar Stimulating Instrument is similar to existing stainless steel stimulating instruments. The device consists of a stainless steel wire with biocompatible electrical insulation applied to selected portions, and proximal connector provided to attach the instruments to a monopolar stimulator. The distal surface of the instrument is non-insulated stainless steel to provide for tissue stimulation. The Rhythmlink International Monopolar Stimulating Instrument with cable assembly is a protected pin design and meets requirements of IEC 60601-1:1988 /A1:1991 /A2:1995 Clause 56.3(c) per 21 CFR 898.12.

Indications for Use:

Rhythmlink International Monopolar Stimulating Instrument is indicated for stimulation of cranial and peripheral motor nerves for location and identification during surgery, including spinal nerve roots. The Rhythmlink International Monopolar Stimulating Instrument is sterile and for single use only.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 22 2008

Rhythmlink International, LLC
c/o James Mewborne
Engineering and Regulatory Manager
1256 First Street South Extension
Columbia, SC 29209

Re: K072736
Trade/Device Name: Rhythmlink Monopolar Stimulating Instrument
Regulation Number: 21 CFR 874.1820
Regulation Name: Surgical nerve stimulator/locator
Regulatory Class: Class II
Product Code: ETN
Dated: December 21, 2007
Received: December 26, 2007

Dear Mr. Mewborne:

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 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), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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, MD

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

Enclosure

K072736

4. Indications for Use Statement

Indications for Use

510(k) Number (if known):

Device Name: Rhythmlink International Monopolar Stimulating Instrument

Indications For Use: Rhythmlink International Monopolar Stimulating Instrument is indicated for stimulation of cranial and peripheral motor nerves for location and identification during surgery, including spinal nerve roots. The Rhythmlink International Monopolar Stimulating Instrument is sterile and for single use only.

Prescription Use __X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Karen A. Baker

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

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