K063560

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510(k) Summary

JAN - 5 2007

Company Name: WR Medical Electronics CO.

Device Name: Hilger Dual-Stim Nerve Stimulator

510(k) Sponsor, Contact:

WR Medical Electronics CO.
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Stillwater, MN 55082
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Summary Date: November 21, 2006

Common Name: Nerve Stimulator

Classification Name: Nerve Stimulator 21 CFR 874.1820, Product Code: ETN, Class II

Predicate Device(s): Preamendment - Hilger Facial Nerve Stimulator
K895838 - Brackman EMG Monitoring System
K021595 - Gyrus ENT Nerve Stimulator

1.0 Description of Device

The Hilger Dual-Stim Nerve Stimulator is a self contained, battery powered device. There is an option to provide a line powered option in the future.

Two modes of nerve stimulation are provided, a Clinical Mode and a Surgical Mode. Table 1.0-1 summarizes the differences in these stimulation modes.

Table 1.0-1: Stimulation Mode Comparison

Feature	Clinical Mode	Surgical Mode
Stimulation Current	Up to 10 mA	Up to 10 mA
Stimulation Pulse Width	0.0006 micro second	0.0002 micro second
Stimulation Frequency	6 Hz	5 Hz

1.1 Variations and Accessories

The only variations of the Hilger Dual-Stim Nerve Stimulator are a battery powered device and a future optional AC line operated device. The safety standards that these two variations meet are the same.

Accessories applied to the Hilger Dual-Stim Nerve Stimulator are probe configurations compatible with the two different stimulation modes:

1. Bipolar Clinical Probe
2. Remote Surgical Probe
3. Monopolar Disposable Probe
4. Silverstein Adapter for Continuous Stimulation (SACS Kit)
5. Hilger Dual-Stim Adapter.

The Hilger Dual-Stim Nerve Stimulator is used in hospitals, operating rooms and clinical environments to support clinical evaluation of nerves. The Hilger Dual-Stim Nerve Stimulator provides the nerve stimulation; the user provides the interpretation of appropriate nerve response.

2.0 Intended use of Device

The intended use of the Hilger Dual-Stim Nerve Stimulator is:

> The Hilger Dual-Stim Nerve Stimulator provides electrical stimulation to nerves during diagnostic and surgical procedures.

3.0 Technological Characteristics

The technical characteristics of the Hilger Dual-Stim Nerve Stimulator are equivalent to those of the predicate devices. The following table summarizes significant feature comparisons.

Feature	Hilger Dual-Stim Nerve Stimulator Under Review	Predicate Hilger (Preamendment)	Predicate Brackman (K895838)	Predicate Gyrus ENT Nerve Stimulator (K021595)
1. Intended Use, Indications for Use	The Hilger Dual-Stim Nerve Stimulator provides electrical stimulation to nerves during diagnostic and surgical procedures.	The Hilger Facial Nerve Stimulator provides electrical stimulation to nerves to aid in nerve location during diagnostic and surgical procedures.	The Brackman EMG Monitor/Stimulator is used to stimulate and monitor cranial nerves.	The Gyrus ENT Nerve Stimulator is intended to provide electrical stimulation to cranial and peripheral motor nerves to aid in nerve location during surgical procedures.
2. Environment of Use	Hospital, Operating Room, Clinic	Hospital, Operating Room, Clinic	Hospital, Operating Room, Clinic	Hospital, Operating Room, Clinic
3. Stimulation Modes	Two Clinical Mode Surgical Mode	One Same as Hilger Dual-Stim Clinical Mode	One Same as Hilger Dual-Stim Surgical Mode	One
4. Stimulation Probes	Bipolar Clinical Probe Remote Surgical Probe Monopolar Disposable Probe	Bipolar Stimulator Probe	Bipolar Stimulator Probe Monopolar Surgical Stimulating Probe Needle and Hook Wire Electrodes	Monopolar and Bipolar
5. Stimulation Current	0 to 10 mA	0 to 10 mA	0.01 to 4 mA	0 to 5 mA
6. Stimulation Pulse Width	Clinical Mode: 0.0006 seconds Surgical Mode: 0.0002 seconds	0.0006 seconds	0.002 seconds	Unknown
7. Stimulation Frequency	Clinical Mode: 6 Hz Surgical Mode: 5 Hz	6 Hz	5 Hz	3, 10, 30 Hz
8. Power	Battery 6 VDC (4 – "C" Cells) Option for AC Power	Battery 6 VDC (4 – "C" Cells)	Battery (Lead Acid) Battery Charger Accessory option	AC Power
9. Safety Standards Compliance	EN/IEC 60601-1 EN/IEC 60601-1-2 EN/IEC 60601-2-10 EN/IEC 60601-2-40	EN/IEC 60601-1 EN/IEC 60601-1-2	EN/IEC 60601-1 EN/IEC 60601-1-2	IEC 601-1 IEC 601-1-2

4.0 Data Summary

Testing of the Hilger Dual-Stim Nerve Stimulator was performed in compliance with the WR Medical Electronics CO. design control process. Testing included:

1. Software verification and validation, and
2. Declaration of safety standard compliance prior to commercial distribution.

5.0 Conclusions

The safety and effectiveness of the Hilger Dual-Stim Nerve Stimulator was demonstrated by testing in compliance with the Design Control process. The intended use and technology of the Hilger Dual-Stim Nerve Stimulator is the same as the predicate devices. No new questions of safety or effectiveness are raised.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

WR Medical Electronics Co.
c/o Gary Syring
Principal Consultant
Quality & Regulatory Associates
800 Lavanger Lane
Stoughton, WI 53589

JAN - 5 2007

Re: K063560
Trade/Device Name: Hilger Dual-Stim Nerve Stimulator
Regulation Number: 21 CFR 874:1820
Regulation Name: Surgical Nerve Stimulator/Locator
Regulatory Class: Class II
Product Code: ETN
Dated: November 21, 2006
Received: November 27, 2006

Dear Mr. Syring:

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 Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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,

M 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

Indications for Use

510(k) Number (if known): K063560

Device Name: Hilger Dual-Stim Nerve Stimulator

Indications for Use:

The Hilger Dual-Stim Nerve Stimulator provides electrical stimulation to nerves during diagnostic and surgical procedures.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Karen H. Baker

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

510(k) Number K063560

Prescription Use X
(Per 21 CFR 801.109)