K061148

11. 510(k) Summary

MAY 10 2006

Company Name: Rhythmlink International, LLC
1256 First Street South Extension
Columbia, SC 29209
Phone: (803) 252-1222
Owner Operator #: 9052354
Establishment Registration #: 1067162

Official Contact Person: James M. Mewborne
Engineering & Regulatory Manager

Summary Date: May 12, 2005

Device Identification: Proprietary Device Name:
Rhythmlink Disc Electrodes

Generic Device Name:
Cutaneous Electrodes

Regulatory Class: Class II

Classification Name: Cutaneous Electrodes

Panel: 882 Neurological Devices, 882.1320
Cutaneous Electrodes

Product Code: GXY

This device has not been previously submitted to the FDA.

Predicate Device(s): Neurolink™ 510(k) Number: K942921
Neuro Supplies 510(k) Number: K991772

Device Description:
Rhythmlink Disc Electrodes are non-invasive, Cutaneous devices are used in the acquisition of signals for the purpose of monitoring and recording Electroencephalograph (EEG), Electroencephalography (EEG), and Evoked Potentials (EP). Rhythmlink Disc electrodes have a disc manufactured with a variety of materials which include; silver, Ag/AgCL, ABS Molded Gold Plated and Gold. See appendix "C" for part numbers and descriptions. The disc is permanently adhered to a lead wire. The joint is then covered by a heat shrink tube or is molded into the disc so as not allow exposed lead wires and provide a strain relief. The lead wires are covered using polyurethane (PU), polyvinylchloride (PVC), Silicone or Teflon cover. The lead wires

terminate using a molded touch proof connector that conforms to DIN 42-802 for electrical safety.

Intended Use:
The Rhythmlink Disc Electrodes are intended for non-invasive use with recording and monitoring equipment, (active and reference), of Electromyography (EMG), Electroencephalograph (EEG) and Evoked Potentials.

This concludes the 510(k) summary.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 10 2006

Rhythmlink International, LLC
c/o Mr. James M. Mewborne
1256 First Street South Extension
Columbia, South Carolina 29209

Re: K061148
Trade/Device Name: Rhythmlink Disc Electrodes
Regulation Name: Cutaneous Electrodes
Regulatory Class: II
Product Code: GXY
Dated: April 24, 2006
Received: April 25, 2006

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 Office of Compliance at (240) 276-0120. 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 (301) 443-6597 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

8. Indications for Use

510(k) Number (if known):

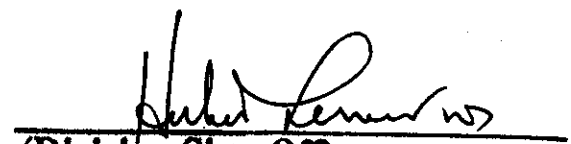
Device Name: Rhythmlink Disc Electrodes

Indications for Use: The Rhythmlink Disc Electrodes are intended for non-invasive use with recording and monitoring equipment, (active and reference), of Electromyography (EMG), Electroencephalograph (EEG) and Evoked Potentials.

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



(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K061148

Revised 8/19/2005