K091055

5. 510(k) Summary

JUN 23 2009

510(k) Summary of Safety and Effectiveness

Company Name:	Rhythmlink International, LLC 1256 First Street South Extension Columbia, SC 29209 Phone: 803-252-1222 FDA Registration #: 1067162 Owner Operator #: 9052354
Official Contact Person:	James M. Mewborne Director of Engineering and Regulatory Affairs Rhythmlink International, LLC 1256 First Street South Extension Columbia, SC 29209 Phone: 803-252-1222 ext. 12 Email: jmewborne@rhythmlink.com
Summary Date:	April 8, 2009
Device Identification:	**Proprietary Device Name:** Rhythmlink Disposable Concentric EMG Needle (Trade name has not been finalized at this time) **Generic Device Name:** Diagnostic Electromyograph Needle Electrode **Regulatory Class:** Class II **Classification Name:** 21 CFR §890.1385, Diagnostic Electromyograph Needle Electrode This device has not been previously submitted to the FDA.
Predicate Device(s):	510(k) Number: ~~K973529~~ K071186 Manufacturer: Ambu® Trade Name: Neuroline Concentric Needle Product Code: IKT

Device Description:	The design of the Rhythmlink Disposable Concentric EMG Needle is similar to existing stainless steel needles used to record muscle activity during electromyograph procedures. The device consists of a needle and a needle body. The inner sensor of the needle is made of stainless steel and is separated from the stainless steel outer cannula by a layer of biocompatible insulation. The needle is sharpened at a 15° angle, creating a recording surface area of 0.07mm^2 or 0.12mm^2, depending upon needle diameter. The needle body houses the component that connects the needle to the leadwire. Inside this body, a gold-plated brass inner sensor pin is crimped onto the end of the inner sensor of the needle and is isolated from the outer cannula of the needle. The needle and pin assembly is then cased in a gold-plated brass outer ring, which is crimped onto the outer cannula. Finally, the entire end of the needle assembly is covered with a polyethylene body that protects the needle and allows the clinician to accurately secure the needle into place. The assembly connects creates a unidirectional connection to the reusable cable, which connects the needle to electromyography recording equipment.
Indications for Use:	Recording muscle activity for Electromyography (EMG) applications. For single patient use only.

This concludes the 510(k) summary.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 23 2009

Rhythmlink® International, LLC
c/o James M. Mewborne
Director of Engineering and Regulatory Affairs
1256 First Street South Extension
Columbia, SC 29209

Re: K091055
Trade/Device Name: Rhythmlink Disposable Concentric EMG Needle
Regulation Number: 21 CFR 890.1385
Regulation Name: Diagnostic Electromyograph Needle Electrode
Regulatory Class: II
Product Code: IKT
Dated: April 9, 2009
Received: April 13, 2009

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 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,

Kesia Alexander for

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

4. Indications for Use Statement

Indications for Use

510(k) Number (if known): Pending K091055

Device Name: Rhythmlink Disposable Concentric EMG Needle

Indications For Use: Recording muscle activity for Electromyograph (EMG) applications. For single patient 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)

JOE HUTTER

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

510(k) Number K091055

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