DEC 0 4 2008

510(k) Summary

Date Prepared [21 CFR 807.92(a)(1)]

June 23, 2008 [Updated 12/3/08]

Submitter's Information [21 CFR 807.92(a)(1)]

Joseph M. Azary
C/o NorthEast Monitoring Inc.
543 Long Hill Avenue
Shelton, CT. 06484

Orchid Design has received authorization to submit this 510(k) on behalf of the sponsor NorthEast Monitoring Inc.

Manufacturer / Sponsor Information:

NorthEast Monitoring Inc.
Two Clock Tower Place, Suite 555
Maynard, MA 01754
Contact: Sherry Strickland (Regulatory / Office Manager)
Contact Tel: (978)461-3992
Contact Fax: (978) 461-5991
Email: sstrickland@nemon.com

FDA-registered medical device under establishment# 1224919.

Trade Name, Common Name, Classification [21 CFR 807.92(a)(2)]

Device Trade Or Proprietary Names

The device trade names are:

- Holter LX Analysis

Device Common, Usual, or Classification Names

Common/Usual Names: Sleep Apnea Analysis Software

Classification Name: Ventilatory Effort Recorder

Classification

Class II, 21 CFR 868.2375, MNR

Class II, 21 CFR 870.2800, DSH

Predicate Device [21 CFR 807.92(a)(3)]

- LifeScreen Apnea (K042745)
- NorthEast Monitoring DR-180+ Oxy Holter (K004007)
- Holter for Windows (K930564)

The device is an option for the Holter software, which was cleared under K930564.

The Holter monitors used with the Holter for Windows software have been cleared under K061293, K041901, and K004007.

The DR-180+ Oxy Holter is a Holter Monitor that can also detect oxygen saturation in blood (SpO2). The DR-180+ Oxy Holter is utilized with the Holter LX Analysis software subject to this submission.

The subject device (Holter LX Analysis software) utilizes the exact algorithm as the predicate device (LifeScreen Apnea). The algorithm is provided to both manufacturers by Biancamed.

The main differences are as follows:

- The Holter LX Analysis can also utilize oxygen saturation in blood (SPO2) when used with the DR180+ Oxy Holter.
- The underlying algorithm remains the same, but the AHI is calculated using oximetry data from a study conducted by Biancamed.
- The Holter LX Analysis is used with North East Monitoring Holter Monitors.

Comparison of test data between the Holter LX Analysis software and the LifeScreeen Apnea device found equivalent results for sensitivity, specificity, accuracy, and positive predictivity. We believe the subject device is substantially equivalent to the predicate device.

Description of the Device [21 CFR 807.92(a)(4)]

Holter LX Analysis is a software option to the Holter for Windows software (K930564).

The software has been designed to detect sleep disordered breathing due to obstructive apneas or hypopneas. The software uses 2 channel ECG and oximetry data collected via the DR180+ Holter Recorder to calculate the patient's Apnea-Hypopnea Index (AHI). The Holter and Oxymetry ECG data obtained by monitoring is not analyzed at the time of recording. After the recording is complete, the data must be downloaded to a compatible NorthEast Monitoring Holter LX Analysis with sleep apnea software system to be analyzed by a healthcare professional.

The sleep apnea monitoring algorithm used in the subject device is the exact algorithm already cleared by FDA.

The Sleep Technician or Physician will utilize standard Holter procedure to hook up the recorder to the patient. The patient will sleep with the recorder for one night in order to collect data. Either the patient or a sleep clinician will note the time that the patient falls asleep and awakens. The sampling rate is 180 samples/second.

The Holter LX Analysis software detects each R-wave. The calculations of AHI are performed. The Holter LX Analysis software can only be used in conjunction with North East Monitoring Holter recorders.

The Holter software was originally cleared by FDA under K930564. The software subject to this 510(k) adds the sleep apnea monitoring capabilities.

The North East Monitoring DR180+ Oxy was cleared under K004007. There are no hardware changes as a result of this addition.

Intended Use [21 CFR 807.92(a)(5)]

Indications For Use: Intended for use on adult patients only as a screening device to determine the need for clinical diagnosis and evaluation by polysomnography based on the patient's score. The ECG recording may be obtained at any location specified by a physician including home, hospital, or clinic. Subjects screened for sleep apnea should have periods of sleep of at least 4 hours duration during which the ECG is predominantly sinus rhythm in nature.

Technological Characteristics [21 CFR 807.92(a)(6)]

NorthEast Monitoring, Inc. believes that the subject device is substantially equivalent to the predicate device.

Performance Data [21 CFR 807.92(b)(1)]

The subject device has been subjected to software validation and comparison studies.

Conclusion [21 CFR 807.92(b)(3)]

We believe the changes are minor and conclude that the subject device is as safe and effective as the predicate devices

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NorthEast Monitoring Incorporated
C/O Mr. Joseph M. Azary
Senior Regulatory Consultant
Orchid Design Orthopedic Solutions
80 Shelton Technology Center
Shelton, Connecticut 06484

DEC 0 4 2008

Re: K081861
Trade/Device Name: Holter LX Analysis
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: II
Product Code: MNR
Dated: November 12, 2008
Received: November 17, 2008

Dear Mr. Azary:

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,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K081861

Device Name: NorthEast Monitoring Inc. Holter LX Analysis

Indications For Use: Intended for use on adult patients only as a screening device to determine the need for clinical diagnosis and evaluation by polysomnography based on the patient's score. The ECG recording may be obtained at any location specified by a physician including home, hospital, or clinic. Subjects screened for sleep apnea should have periods of sleep of at least 4 hours duration during which the ECG is predominantly sinus rhythm in nature.

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

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K081861