K070014

NorthEast Monitoring, Inc.

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advancing Holter technology

510(k) Summary

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

December 29, 2006

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

MAY 25 2007

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

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

Sponsor / Manufacturer
NorthEast Monitoring Inc.
Two Clock Tower Place, Suite 555
Maynard, MA 01754

FDA establishment registration# 1224919.

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

Trade names are:

- Auto Detect
- Telaheart DR200/HE-a
- DR200/HE-a

Device Common, Usual, or Classification Names:

Ambulatory ECG Recorder, Ambulatory Electrocardiograph (without analysis), Telephone electrocardiograph transmitter and receiver

Classification:

Class II, 21 CFR 870.2800, MWJ

Class II, 21 CFR 870.2920, DXH

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

- NorthEast Monitoring Telaheart – K061293
- Heartrak Smart AT – K033451

Auto Detect feature compared to Telaheart

The subject device (DR200/HE-a and Telaheart DR200/E-a) is identical to the predicate device (Telaheart) with one difference. The devices have the **same** indications for use, identical physical and electrical characteristics, and identical materials as the predicate device. The main difference between the subject device and predicate device are as follows:

- The subject device includes the Auto Detect feature. The Auto Detect feature was included in the software code of the Telaheart, but was not enabled with the Telaheart units distributed.

DR200/HE compared to Heartrak Smart AT

The subject device has the same indications for use as the predicate device. Both devices have automatic detection features, are loop memory recorders, and can transmit data via telephone. The differences are as follows:

- The Heartrak Smart AT uses 2 AA batteries
- The devices have minor differences dimensionally
- The Heartrak Smart AT is only an event recorder and cannot be used as a Holter Monitor.

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

NorthEast Monitoring will offer versions with the Auto Detect feature.

- Telaheart DR200/E-a Event Recorder with Auto Detect feature (using a black background).
- DR200/HE-a Holter and Event Recorder with Auto Detect feature (using white background).

The Auto Detect feature can be used as a looping event recorder to capture events automatically or when activated by the patient. When one or more events are captured the patient may transmit his/her recordings transtelephonically. The device stores the events in memory. There is a display counter for the events and an audible beep to remind the user to transmit the data to the physician.

The data obtained during monitoring is not analyzed at the time of recording. After the recording is complete, the data must later be downloaded to a compatible NorthEast Monitoring Holter or Event

analysis system. The Holter Analysis Software was cleared by FDA under K930564. The TelePro software was included in the Telaheart 510(k) cleared by FDA under K061293.

The device is not intended to replace real time telemetry monitoring for patient suspected of having life threatening arrhythmias.

The device has the identical hardware as the Telaheart device (cleared by FDA) and is powered by one 1.5 volt AA alkaline battery (MN1500 or the equivalent), one AA rechargeable NiMH (nickel metal hydride) battery, or one AA Eveready Lithium L91 battery. Batteries should not be re-used for a second patient. The batteries are not included; users are instructed to purchase 2 AA batteries.

The device is compatible with standard silver / silver chloride ECG electrodes. Electrodes are not provided with the subject device. The user is instructed to purchase standard silver / silver chloride ECG electrodes.

Physical and Electrical Specifications:

Characteristic	**Specification**
Dimensions	**8.6cm (length) x 6.0cm (width) x 2cm (depth)**
Weight	**70.9 grams (2.5 oz) without battery** **99.3 grams (3.5 oz) with battery**
Recording Bandwidth	**0.05 to 70 hertz in 180 samples/sec mode**
Prefilter Sampling Rate	**720 samples/sec**
Data Stored	**In 180 samples/sec mode, data stored at 180 samples/sec (4 sample average), in 360 samples/sec mode, data stored at 360 samples/sec (2 sample average), in 720 samples/sec mode, data stored at 720 samples/sec.**
Pacemaker Sensitivity	**2 millivolts**
Pacemaker Pulse Duration	**150 to 2500 microseconds**

Electrical Safety and Electromagnetic Compatibility

The hardware and electrical circuitry has not changed. The subject device conforms to the following standards:

- IEC 60601-1 Medical Electrical Equipment Part 1: General Requirements for Safety
- IEC 60601-1-2-47 Medical Electrical Equipment Part 2 – 47: Particular Requirements for the Safety including Essential Performance of Ambulatory Electrocardiographic Systems.

  ***IEC 60601-2-47 is the equivalent to AAMI / ANSI EC38:1998.**
- EN 55022 Class B ITE emissions

Patient Contacting Materials

The subject device does not make direct contact with the patient. The subject device is used with commercially available electrodes purchased by the customer.

Reprocessing, Cleaning, Disinfection, and Sterilization

The subject device does not make direct contact with the patient and does not require sterilization. The Operator's Manual includes a section on maintenance and care, which includes cleaning and infection control.

Software

The software in the subject device is identical to the software included in the Telaheart device K061293. The only difference is the Auto Detect feature was not enabled in the Telaheart device when it was sold to the public. The Auto Detect feature was not utilized in the Telaheart, but existed in the software code.

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

The Telaheart Digital Recorder can be used in Holter mode and Event Recorder mode.

Holter Mode

Detection of Arrhythmias, Efficacy of Pharmacological Treatment, and Pacemaker Evaluation.

Event Recorder

The Telaheart event recorder module is a patient activated device designed to record and for diagnostic evaluation of transient symptoms (such as dizziness, palpitations, syncope, and chest pain). Once data is recorded, the data is transmitted via telephone for evaluation.

The device includes the Auto Detect feature which can be used as a looping event recorder to capture events automatically or when activated by the patient. When one or more events are captured the patient may transmit his/her recordings transtelephonically.

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 and passed electrical safety and EMC testing requirements.

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, Inc.
C/O Joseph M. Azary
Azary Technologies, LLC
543 Long Hill Avenue
Shelton, CT 06484

MAY 25 2007

Re: K070014
Trade/Device Name: Auto Detect for Telaheart
Regulation Number: 21 CFR 870.2800
Regulation Name:Ambulatory ECG Recorder, Ambulatory Electrocardiograph (without analysis)
Regulatory Class: Class II
Product Code: MWJ, DXH
Dated: May 17, 2007
Received: May 21, 2007

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.

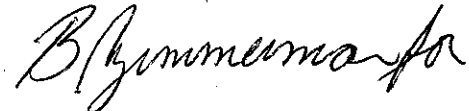
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Bram D. Zuckerman, MD
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K070014

Device Name: Auto Detect for Telaheart

Indications For Use:

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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 Cardiovascular Devices
510(k) Number K070014