K061293

AUG 2 5 2006

510(k) Summary

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

May 5, 2006

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

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. NorthEast Monitoring Inc. located at Two Clock Tower Place, Suite 360, Maynard, MA 01754, is an FDA-registered medical device under establishment# 1224919.

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

Trade names are:

Telaheart Digital Recorder

Device Common, Usual, or Classification Names:

Ambulatory ECG Recorder, Ambulatory Electrocardiograph (without analysis)

Classification:

Class II, 21 CFR 870.2800, MWJ

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

- NorthEast Monitoring SD360 - K041901
- Braemar ER800 – K030856

Telaheart compared to the SD360

The subject device has the **same** indications for use as the predicate when used in Holter mode. The subject device adds the Event Recording mode. The main differences between the subject device and predicate device are as follows:

- The subject device (Telaheart) can be used as an Event Recorder.
- Event information can be transmitted via telephone.
- The LCD screen in the subject device is slightly larger.
- The subject device can be used with patient cables with 2, 5, or 7 leads. The predicate device did not have the option of use with a 2 lead cable. The 2 lead cables are used for event recording.

Telaheart compared to the ER800

The subject device has the same indications for use as the predicate (ER800). The devices comply with the same safety standards, have the same power supply (1 AA battery), have pacemaker detection ability, use belt clips, and transmit data via telephone. The differences are as follows:

- The ER800 does not have an LCD
- The ER800 uses Flash cards instead of SD cards

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

An ambulatory monitor, sometimes called a Holter, is a painless method to monitor the heart beat for a period of time (such as 24 hours, 48 hours, or 72 hours). The Holter is a small recording device that records the heart beat while being worn by the patient.

The physician or technician places electrodes and wires on the patient. The wires are connected to the Holter or digital recorder.

The Telaheart Digital Recorder has two modes that allow it to be used either as a standard Holter monitor or a looping Event recorder. The device is designed to facilitate ambulatory cardiac monitoring on the order of a physician, of those patients (including infants weighing less than 10 kg) who may benefit from such monitoring.

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 (TelePro Software) to be analyzed. The Holter Analysis Software was cleared by FDA under K930564.

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

The Telaheart Digital Recorder package includes:

- Telaheart Digital Recorder
- Operation Manual
- SD Card
- Patient Cable

The Telaheart digital recorder 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.

The Telaheart digital recorder uses NorthEast Monitoring Telaheart patient cables with either 2, 5, or 7 patient leads. The patient cable connects to the recorder via a connector on the recorder. A patient cable is provided with the Telaheart Digital Recorder.

The Telaheart has an LCD that is used to display the time of day (during the recording), prompts and error messages (during the hookup procedure or during recording), or lead quality (during the hookup procedure).

The data collected by the Telaheart digital recorder is stored on a removable SD Card.

The Telaheart is packaged in a plastic bag in a cardboard shipping carton. The shipping carton will also include a patient cable and an SD Card.

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 device has been tested and passed electrical safety and EMC requirements utilizing 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, and EN 60601-1-2 Medical Electrical Equipment Part 1-2: General Requirements for Safety - Collateral Standard Electromagnetic Compatibility – Requirements and Tests. The test results have been attached in Annex 2.

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 Telaheart digital recorder includes software. The device is used with both Holter Analysis Software and the Telepro software.

The software in the Telaheart and the Telepro software have been determined to be minor level of concern. The Telaheart is not intended to replace real time telemetry monitoring for patients suspected of having life-threatening arrhythmias. The software has successfully passed all validation testing.

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

Patient activated device designed to record and for diagnostic evaluation of transient symptoms. Once data is recorded, the data is transmitted via telephone for evaluation.

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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

AUG 2 5 2006

Northeast Monitoring, Inc.
c/o Mr. Joseph Azary
President
Azary Technologies, LLC
543 Long Hill Avenue
Shelton, CT 06484

Re: K061293
Trade/Device Name: Telaheart Digital Recorder
Regulation Number: 21 CFR 870.2800
Regulation Name: Medical Magnetic Tape Recorder
Regulatory Class: II
Product Code: MWJ
Dated: July 25, 2006
Received: July 31, 2006

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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

Indications for Use

510(k) Number (if known): **K061293**

Device Name: NorthEast Monitoring Inc. Telaheart Digital Recorder

Indications For Use:

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.

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)

Donna R. Vechiset

(Division Sign-Off)
Division of Cardiovascular Devices

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