

AUG 31 2004

510(k) Summary

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

July 9, 2004

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)]

Device trade names are: NorthEast Monitoring SD360 Digital Recorder, SD360 Digital Holter Recorder
Common Name: Ambulatory ECG Recorder, Ambulatory Electrocardiograph (without analysis)
Classification: Class II, 21 CFR 870.2800, MWJ

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

- NorthEast Monitoring DR180 II Holter Recorder – K001288

The subject device has the same indications for use as the predicate. Both the subject device and predicate device can be used for 3 channel recording. The main differences between the subject device and predicate device are as follows:

- The subject device is smaller and thinner.
- The subject device weighs less.
- The subject device requires only one AA battery (as opposed to two AA batteries required by the predicate).
- The subject device does not have 12 lead capabilities (this was not a heavily used option in the predicate device).
- The LCD screen in the subject device is smaller. The LCD screen of predicate device showed waveforms, whereas the LCD screen of the subject device shows lead quality as a numeric value.
- The subject device uses SD cards instead of flash cards for memory. The SD cards are smaller, but have the same memory capabilities as the flash 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. Typically the patient is asked to write down a diary of daily activity including the time and character of any symptoms.

The patient can push a patient event button to mark an event. The patient must write down details about the event in their diary so that physician or technician can relate the event to specific symptoms or activities.

[REDACTED]

The NorthEast Monitoring SD360 Digital Recorder is a holter monitor designed to facilitate the ambulatory cardiac monitoring, on the order of a physician, of those patients who may benefit from such monitoring including but not limited to those with complaints of palpitations, syncope, chest pains, shortness of breath, or those who need to be monitored to judge their current cardiac function, such as patients who have recently received pacemakers.

The SD360 Digital Recorder package includes:

- SD360 Digital Recorder
- Operation Manual
- SD Card
- Patient Cable
- Pouch

The data obtained by 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 analysis system to be analyzed. The Holter Analysis Software was cleared by FDA under K930564.

The SD360 is not intended to replace real time telemetry monitoring for patients suspected of having life-threatening arrhythmias.

The SD360 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.

510(k) Notification
NorthEast Monitoring SD360 Digital Recorder

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 SD360 digital recorder uses NorthEast Monitoring SD360 patient cables with either seven leads or five leads for a 3-channel holter recording. The patient cable connects to the recorder via a 9-pin female connector on the recorder. A patient cable is provided with the SD360 Digital Recorder.

The SD360 has a small LCD that is used to display either time of day (during the recording), error messages (during the hookup procedure or during recording), or lead quality (during the hookup procedure).

The data collected by the SD360 digital recorder is stored on a removable SD Card. To store 24 hours in normal mode, the minimum capacity of the SD Card should be 28 megabytes; 56 megabytes are required for 24 hours in high resolution mode. To store 24 hours in 360 samples/sec mode, 112 megabytes are required. To store 24 hours in 720 samples/sec, 224 megabytes are required. Double all storage requirements for 48 hour recordings, and triple them for 72 hour recordings. The SD360 is provided with an SD memory card with at least 32 megabytes.

The SD360 is packaged in a plastic bag in a cardboard shipping carton. The shipping carton will also include a patient cable and a pouch. The pouch is used by the patient to hold the digital recorder while in use.

The physician or technician can optionally use a PC as an interface to key in patient information. If a PC were used, the patient information would be keyed into the SD card using the NorthEast Monitoring Holter Analysis software (cleared under a separate 510k).

Another option for entering patient information is through the use of a PDA (i.e. Palm Pilot). Patient information such as patient name, sex, date of birth, identification number, scan number, hookup tech name or initials, physician name, indications, and medications.

Physical and Electrical Specifications:

| Characteristic | Specification |
|--------------------------|--|
| Dimensions | 8.7cm (length) x 6.5cm (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; 0.05 to 150 hertz in 360 or 720 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 | 100 to 2500 microseconds |

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

5. Detection of Arrhythmias: The NorthEast Monitoring, Inc. SD360 Digital Recorder is indicated for use in continuous monitoring of cardiac rhythm when intermittent arrhythmia are suspected due to patient symptoms such as palpitations, transient ischemic attacks (TIAs), syncope (fainting), or other such symptoms as determined by the physician.
6. Efficacy of Treatment: The NorthEast Monitoring Inc. SD360 Digital Recorder is indicated for use to determine whether current pharmacological treatment(s) of known arrhythmia is effective by measuring the frequency and duration of the arrhythmia compared to the frequency and duration prior to treatment.
7. Pacemaker Evaluation: The NorthEast Monitoring Inc. SD360 Digital Recorder is indicated for use to evaluate the function of implanted pacemakers to insure that the pacemaker is functioning within prescribed limits.
8. The NorthEast Monitoring SD360 Digital Recorder is to be used by or on the order of a physician.

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

NorthEast Monitoring, Inc. believes that the subject device is substantially equivalent to the predicate device. The subject device has the same indications for use as the predicate.

The main technological difference is the device is smaller, thinner, weighs less, uses only one battery, does not have 12 lead capabilities, uses SD cards instead of flash cards for memory, and can be used with a Palm Pilot to enter patient information.

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.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 31 2004

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

Re: K041901

Trade Name: Northeast Monitoring SD360 Digital Recorder
Regulation Number: 21 CFR 870.2800
Regulation Name: Medical Magnetic Tape Recorder
Regulatory Class: II (two)
Product Code: MWJ
Dated: July 14, 2004
Received: July 14, 2004

Dear Mr. Azary:

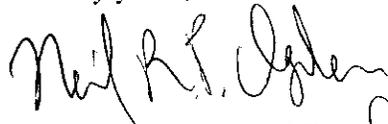
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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 (301) 594-4648. 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/dsma/dsmamain.html>

Sincerely yours,



Bram D. Zuckerman, M.D. *for 807*
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K041901

Device Name: NorthEast Monitoring Inc. SD360 Digital Recorder

Indications For Use:

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3. Pacemaker Evaluation: The NorthEast Monitoring Inc. SD360 Digital Recorder is indicated for use to evaluate the function of implanted pacemakers to insure that the pacemaker is functioning within prescribed limits.
4. The NorthEast Monitoring SD360 Digital Recorder is to be used by or on the order of a physician.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(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)

Neil R. Pugh
(Division Sign-Off)
Division of Cardiovascular Devices

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510(k) Number K041901

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