3/23/99

K983576

510(k) Summary

The DR180-R/Oxy Holter and Pulse Oximetry Recorder is the predicate device (DR180 Holter recorder, 510(k) K960925) with the addition of a Nonin Xpod pulse oximetry probe. The probe cable is attached to the DR180 with the electrode lead wires. ECG and pulse oximetry are recorded simultaneously for periods up to ~~48~~ 24 hours. This data is recorded onto PCMCIA Flashdisk memory storage cards. When recording is complete, the card is removed from the DR180-R/Oxy, inserted into a slot in the analysis system, and the data is downloaded and analyzed as previously. The oximetry data is simply presented to the operator; no manipulation or editing is allowed.

The Xpod was clinically tested (human subjects) by its manufacturer, Nonin, and found to have <2% error. NorthEast Monitoring tested the DR180-R/Oxy using a pulse oximetry simulator, resulting in even greater accuracy.

The DR180-R/Oxy Operator's Manual is identical to the previous DR180 Operator's Manual with the addition of oximetry capability. The Holter for Windows Operators Manual is identical to the previous with the addition of the oximetry option.

To the best of our knowledge, no other manufacturer has added oximetry capabilities to a Holter recorder at this date.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 23 1999

Mr. Rodney L. Cambre
Director of Regulatory Affairs
and Quality Assurance
Northeast Monitoring, Inc.
730 Boston Post Road Suite 22
Sudbury, MA 01776

Re: K983576
DR180-R/Oxy
Regulatory Class: II (two)
Product Code: FLL
Dated: January 26, 1999
Received: January 28, 1999

Dear Mr. Cambre:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this

response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

Thomas J. Callahan

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K983576

Device Name: DR180-R/Oxy

Indications For Use:

NORTHEAST MONITORING DR180-R/Oxy

1.) Detection of Arrhythmias: The NorthEast Monitoring DR180-R/Oxy is indicated for use for long-term monitoring of cardiac rhythm when intermittent arrhythmias are suspected due to patient symptoms such as palpitations, transient ischemic attacks (TIA's), syncope (fainting), or other such symptoms as determined by the physician.

2.) Efficacy of Treatment: The NorthEast Monitoring DR180-R/Oxy is indicated for use to determine if current pharmacological treatment of known arrhythmias is effective by measuring the frequency and duration of the arrhythmia compared to the frequency and duration prior to treatment.

3.) Pacemaker Evaluation: The NorthEast Monitoring DR180-R/Oxy is indicated for use to evaluate the function of implanted pacemakers to insure that the pacemaker is functioning within prescribed limits.

4.) Trending of oxygen saturation (SpO2) in the blood for periods of up to 24 hours. If the device is to be used for home monitoring, periods of activity or excessive movement are to be omitted due to the artifact that would be generated.

5.) The NorthEast Monitoring DR180-R/Oxy is to be used only on the order of a physician.

(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, Respiratory,
and Neurological Devices
510(k) Number K983576

Prescription Use X
Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)