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5 510(k) Summary of Safety and Effectiveness

JUN 20 2008

Date:
January 29, 2008

Submitter:
GE Medical Systems *Information Technologies*
8200 West Tower Avenue
Milwaukee, WI 53223 USA

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Device Trade Name:
ApexPro Telemetry System

Common /Usual Name:
Telemetry Monitoring System

Classification Names:
21 CFR 870.1025 Physiological Patient Monitor (with arrhythmia detection or alarms

Predicate Devices:
K032369 ApexPro Telemetry System
K033365 ApexPro FH Telemetry System
K980299 Apex OXIMETER

Device Description:
The ApexPro Telemetry System provides clinicians with patient data while allowing for patient mobility. The system consists of the following main components:

- The patient worn data acquisition transmitters
- Receiver Infrastructures
- Computer platforms hosting the ApexPro Software
- Computer platforms hosting the central station application
- Accessories to the patient-worn data acquisition transmitters
- Serviceability tools

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Intended Use:

The ApexPro Telemetry System is intended for use under the direct supervision of a licensed healthcare practitioner. The system is designed to acquire and monitor physiological data for ambulating patients within a defined coverage area. The system processes this physiological data to detect various ECG arrhythmia events and select physiological parameter limit violations.

The ApexPro Telemetry System is intended to be installed in the hospital or clinical environment in order to provide clinicians with patient physiological data, while allowing for patient mobility. These systems are typically deployed in sub acute care areas in hospitals or clinical sites where patient mobility can enhance the effectiveness of the medical procedures administered.

The physiological parameters monitored include ECG, non-invasive blood pressure, non-invasive temperature and SpO2. The ApexPro Telemetry System is intended to provide ECG data via Ethernet to the computer platform for processing. The ApexPro Telemetry System is also intended to provide physiologic data over the Unity Network to clinical information systems for display.

Technology:

The ApexPro Telemetry System employs the same functional technology as the predicate devices.

Test Summary:

The subject of this 510(k) is a design modification for the ApexPro Telemetry System. The ApexPro Telemetry System complies with the voluntary standards as detailed in Section 9 (Declaration of Conformity and Summary Reports) of this submission. The following quality assurance measures were applied to the development of the ApexPro Telemetry System:

- Risk Analysis
- Requirements Review
- Design Reviews
- Testing on Unit Level (Module verification)
- Integration testing (System Verification)
- Final Acceptance testing (Validation)
- Performance testing
- Safety and environmental testing

Conclusion:

The results of these measurements demonstrated that the ApexPro Telemetry System is as safe, as effective, and performs as well as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 20 2008

GE Medical Systems Information Technologies
c/o Mr. Bernard Sandler
Regulatory Affairs Specialist
8200 West Tower Avenue
Milwaukee, WI 53223

Re: K080251
Trade Name: ApexPro Telemetry Systems
Regulation Number: 21 CFR 870.1025
Regulation Name: Physiological Patient Monitor (with arrhythmia detector or alarms)
Regulatory Class: Class II (two)
Product Code: MHX
Dated: May 23, 2008
Received: May 27, 2008

Dear Mr. Sandler:

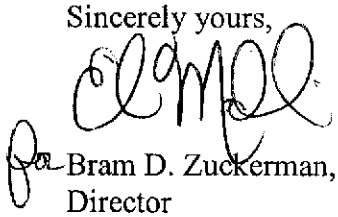
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4 Indications for Use Statement

510(k) Number: K080251

Device Name: ApexPro Telemetry System

Indications for Use:

The ApexPro Telemetry System is intended for use under the direct supervision of a licensed healthcare practitioner. The system is designed to acquire and monitor physiological data for ambulating patients within a defined coverage area. The system processes this physiological data to detect various ECG arrhythmia events and select physiological parameter limit violations.

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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 K080251