K980299

APR 24 1998

510(k) Summary of Safety and Effectiveness

1. Submitter

Marquette Medical Systems
8200 West Tower Avenue
Milwaukee, WI 53223 USA

Establishment Registration Number
2124823

Contact Name / Telephone Number
David Wahlig
Corporate Regulatory Affairs
Marquette Medical Systems

Phone: (414) 362-2090

Date: 26 January 98

2. General Information

Trade/Proprietary Name

Marquette's name for this device is the APEX OXIMETER.

Common/Usual Name

This device is commonly known as pulse oximeter.

Device Classification

This device is viewed as a component of a system. The APEX OXIMETER adds modularity to Marquette's telemetry product line. It is intended for portable patient monitoring of an ambulating patient's oxygen saturation and pulse rate. The oxygen saturation calculations for the Apex Oximeter is performed identically to the method used in the Nonin 8500 series hand held pulse oximeter. The oximeter generates serial communications with a custom protocol to communicate with the CD Telemetry System. Therefore, the submitted device takes on the same classification level as the predicate oximeter.

FDA determined the predicate devices to be: Nonin Model 8500 Hand Held Pulse Oximeter and Nonin Model 9500 Finger Clip Pulse Oximeter were determined to be Class II devices. The CD Telemetry System was determined to be a Class III.

Performance Standards

Performance standards (Section 514 of the Act) have not yet been established for the device that is the subject of this premarket notification submission.

3. Legally Marketed Predicate Device(s)

This submission is being filed as a modification to an existing device. It is being filed in support of the position that the proposed modified device, the APEX OXIMETER, is substantially equivalent to devices already in legal commercial distribution: Nonin Model 8500 Hand Held Pulse Oximeter (K893221); Nonin Model 9500 Finger Clip Pulse Oximeter (K942248); Marquette CD Telemetry System (K891104).

4. Device Description and Intended Use

This device is viewed as a component of a system. The APEX OXIMETER adds modularity to Marquette's telemetry product line. It is intended for portable patient monitoring of ambulating patient's oxygen saturation and pulse rate. The oxygen saturation calculations for the Apex Oximeter is performed identically to the method used in the Nonin 8500 series hand held pulse oximeter. The oximeter generates serial communications with a custom protocol to communicate with the CD Telemetry System

5. Test Summary & Conclusion

Various reliability and software testing was performed on the product, and the results indicated that the APEX OXIMETER met the requirements of its intended use. Marquette Medical Systems has demonstrated that use of the APEX OXIMETER is as safe and effective, and performs substantially equivalent its predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 24 1998

Mr. David Wahlig
Marquette Medical Systems, Inc.
8200 West Tower Avenue
Milwaukee, WI 53223

Re: K980299
APEX Oximeter
Regulatory Class: II (two)
Product Code: 74 DQA
Dated: January 26, 1998
Received: January 27, 1998

Dear Mr. Wahlig:

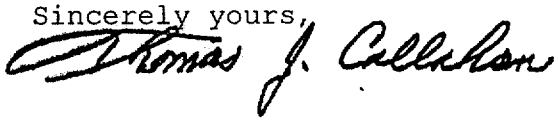
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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" (21 CFR 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/dsmamain.html".

Sincerely yours,



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): Unknown; 510(k) filed on 26 January, 1998

Device Name: APEX Oximeter

Indications For Use:

This device is viewed as a component of a system. The APEX Oximeter adds modularity to Marquette's CD Telemetry System product line. The Apex Oximeter is intended for portable patient monitoring of an ambulating patient's oxygen saturation and pulse rate.

This device is intended to be used by personnel trained in the use of the equipment. It is intended to be used within the hospital/facility environment.

(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 K980299

Prescription Use ✓ OR Over-The-Counter Use ___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)