K060616

JUN 29 2006

510(k) SUMMARY

Manufacturer's Name, Contact Person, Address, Phone, Fax, Email, Date Prepared

Mfr Name:	PHD Medical
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Date Prepared: January 6, 2006

Device Name, Common/Generic Name and Classification Name

Proprietary Name: NPOSES

Common/Usual Name: Pulse Oximeter Data Management Software

Classification Name: Oximeter

Predicate Devices

nVISION Data Management Software (K033307), manufactured by Nonin Medical, Inc.

Description of the Device

The PHD Medical NPOSES (Nocturnal Pulse Oximetry Study Expert System) application scores data in the patient history, physician comments and test results to automatically produce an analysis report as input to the identification of pediatric obstructive sleep apnea which is presented to Respiratory Specialists and Medical Doctors. The suggested diagnosis is used to assist the Medical Director in the diagnosis of the severity of obstructive sleep apnea. The application enables the efficient processing of patient sleep evaluation studies while allowing the medical staff to concentrate on critical cases.

Intended Use of the Device

The intended use of NPOSES (Nocturnal Pulse Oximetry Study Expert System) software is to provide information to a Medical Doctor specializing in sleep medicine to assist in the timely diagnosis of pediatric obstructive sleep apnea (OSA). NPOSES in itself is not a diagnosis tool. It is a management tool which allows medical personal to input and view data relating to a study and give feedback which may be used by an MD to form a diagnosis.

Technological Characteristics

The software will operate under Windows 98, Windows ME, Windows NT 4.0 with Service Pack 6 (SP6), Windows 2000, or Windows XP or later. Also under Linux: Debian, LinuxOS, RedHat or Mantriva. NPOSES and the predicate device can be used on a personal computer.

Performance Data

Testing was performed to confirm that NPOSES software is capable of meeting all of its intended functional requirements. NPOSES passed all tests.

Substantial Equivalence

NPOSES does not have a significant descriptive difference in comparison to the selected predicate marketed software device. There are no technological characteristics which impact safety and effectiveness. Based on our review of the candidate predicate device's description, intended use, method of operation and performance specifications vs. NPOSES, it is concluded that NPOSES is substantially equivalent to the predicated device.

Conclusion

The cumulative test results demonstrated the functionality, safety and effectiveness of NPOSES, as well as its substantial equivalence to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 29 2006

PHD Medical
C/O Ms. Nancy Ruth
Associate Director, Regulatory Services
CanReg, Incorporated
4 Innovation Drive
Dundas, ON
CANADA L9H 7P3

Re: K060616
Trade/Device Name: NPOSES
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: June 2, 2006
Received: June 5, 2006

Dear Ms. Ruth:

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,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: NPOSES

Indications For Use:

The intended use of NPOSES (Nocturnal Pulse Oximetry Study Expert System) software is to collect, analyze, report and archive oximetry trend data to provide information to a Medical Doctor specializing in sleep medicine, as a supplemental tool to assist in the timely diagnosis of pediatric obstructive sleep apnea (OSA).

NPOSES is intended for use by an MD/Respiratory Specialist through the following process steps (1) recording and transferring data from a pulse oximeter to a computer in order to maintain unique records per patient of pulse oximetry data, (2) analyzing, reviewing and validating patient data and summary statistics according to customized, user-selected parameters, and (3) generating and archiving reports.

NPOSES in itself is not a diagnosis tool. It is a decision management tool which allows medical personnel to upload and view data related to a sleep study and provide output reports as feedback which may be used by an MD to form a diagnosis.

Prescription Use __X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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)

...Sign-Off)
...n of Anesthesiology, General Hospital
...ion Control, Dental Devices
...Number K061...