K082968

Non-Confidential Summary of Safety and Effectiveness

30-Dec-2008

JAN – 2 2009

Company

ApneiCare, LLC
PO Box 418
Worthington, OH 43085

Official Contact:

ApneiCare, LLC
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P 614-774-6003

Proprietary or Trade Name:

ApneiCare Connection Center / Internet Analysis

Common/Usual Name:

Polysomnography Scoring Software

Classification Information:

Regulation Number: 21 CFR 868.2375
Regulation Name: Ventilatory Effort Recorder
Regulatory Class: Class II
Product Code: MNR

Device: ApneiCare Connection Center / Internet Analysis

Predicate Devices: Vitascore BV - Vitascore - 510(k) K072014
Respironics - ProFox Software - 510(k) K001708

Device Description:

ApneiCare Connection Center / Internet Analysis is composed of two components: The Connection Center and the Internet Analysis Application. The ApneiCare Connection Center and the ApneiCare Internet Analysis Application function in a client server relationship.

The purpose of ApneiCare Connection Center is to download stored data from supported devices that are typically used to evaluate sleep and sleep related respiratory disorders. It allows users to

export sleep data, and interact with the ApneiCare Internet Analysis to run analysis reports on sleep studies.

ApneiCare Connection Center will operate under Windows XP and Windows Vista; but more importantly is built on Microsoft .NET Framework. The ApneiCare applications have been designed on Microsoft .NET Framework to take advantage of the latest layer of abstraction to allow for Operating System changes in the future while lowering the probability of the application being negatively impacted by operating system changes. "ApneiCare Connection Center is responsible for binding patient information to the study and downloading the data off of the source device. The ApneiCare Connection Center is a small program on the PC with functionality limited to that of general purpose data entry, storage and communication, it performs no data manipulation functions. The data is then communicated to ApneiCare Internet Analysis via an Internet connection, where the sleep analysis and reporting is performed. The ApneiCare Connection Center has built in features to insure that required patient information is entered and that internet connectivity is available. All Internet activity is encrypted and secure. Each transaction between ApneiCare Connection Center and ApneiCare Internet Analysis is conducted over at least 128-bit HTTPS using private and public encryption.

Saved tests can be converted into ASCII format for importing to spreadsheets or databases. The patient information consists of the patient name and address, an ID number, patient insurance and other relevant information. The ApneiCare Internet Analysis Application provides information pertaining to the waveform patterns, such as those of the SpO_2 and pulse recording, to aid physicians with the diagnosis of sleep and breathing disorders. Individual desaturation and respiratory events in series (cycles) are scored by algorithm. These patterns are identified using DPAR objects. In addition, to the Internet Analysis the ApneiCare Internet Analysis DPAR Case Viewer application module may also be used to manually score events and visually compare and analyze across multiple channels of data.

The ApneiCare Internet Analysis Application is primarily a mathematical data processing function that reports cycling respiratory events across multiple channels of data. The functionality of the ApneiCare Internet Analysis Application is not time critical or real time. Therefore delays in internet transfer do not impact functionality. The ApneiCare Internet Analysis Application also performs a data management functions which allows the various authorized users of the system to access, view, report and analyze individual cases. The ApneiCare Connection Center is compiled for .NET 2.0, and dependent upon the .NET Framework as the OTS. .NET 2.0 is provided by Microsoft and contains the CLR (Common Language Runtime) which has abstracted ApneiCare Connection Center away from specific Microsoft Windows Operating System Versions. The ApneiCare Internet Analysis application is a server application, runs on Windows Server 2008 and SQL Server 2005, and .NET 3.5, it is managed in a centralized location by ApneiCare.

Indications for Use:

ApneiCare Connection Center/Internet Analysis is a software device, intended to be used as an aid in the diagnosis of sleep and respiratory related sleep disorders. ApneiCare Connection Center/Internet Analysis is used for analysis (semi-automatic and manual rescoring), display, redisplay (retrieve), edit, summarize, to generate user defined reports, networking and managing of data received from devices that are typically used to evaluate sleep- and sleep related respiratory disorders. ApneiCare Connection Center/Internet Analysis software also provides scoring of desaturation events as they related to sleep breathing disorders.

ApneiCare Connection Center/Internet Analysis is intended to be used as an information and decision management tool to import/record and transmit/transfer data typically captured to evaluate sleep and respiratory related sleep disorders.

ApneiCare Connection Center/Internet Analysis itself is not a diagnostic tool. It is an information and decision management tool which allows medical personnel to upload, view, and score data related to a sleep study and provide output reports to a physician.

The use of this software is to be under the supervision of a physician, sleep technologies, or clinician.

Device Attributes:

Attributes	
Intended use General	ApneiCare Connection Center/Internet Analysis is intended to be used as an aid in the diagnosis of sleep and respiratory related sleep disorders. The ApneiCare Connection Center and ApneiCare Internet Analysis Application is intended to be used as an information and decision management tool to import/record and transmit/transfer data typically captured to evaluate sleep and respiratory related sleep disorders.
Intended use Specific	ApneiCare Connection Center/Internet Analysis is intended to be used as an aid in the diagnosis of sleep and respiratory related sleep disorders. The ApneiCare Connection Center and ApneiCare Internet Analysis Application is intended to be used as an information and decision management tool to import/record and transmit/transfer data typically captured to evaluate sleep and respiratory related sleep disorders.
Environments of use	home care, nursing home, sub-acute institutions, sleep clinics or hospitals
Patient Population	All individuals
Contraindications	None
Prescription	Prescription
Materials	None in patient contact
Performance	Comparative testing demonstrate equivalence to the predciate

Differences Between Other Legally Marketed Predicate Devices

The is viewed as substantially equivalent to the following predicate devices – Vitascore K072014 ProFox Software K001708.

There are no significant differences that affect the safety or effectiveness of the intended device as compared to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

ApneiCare, LLC
C/O Mr. Paul E. Dryden
President
ProMedic, Incorporated
24301 Woodsage Drive
Bonita Springs, Florida 34134-2958

JAN - 2 2009

Re: K082968
Trade/Device Name: ApneiCare Connection Center/Internet Analysis
Regulation Number: 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: II
Product Code: MNR
Dated: October 2, 2008
Received: October 6, 2008

Dear Mr. Dryden:

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.

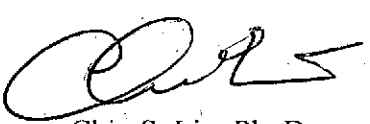
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 S. Lin, Ph. D
Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K082968

Device Name: ApneiCare Connection Center / Internet Analysis

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Prescription Use XX (Part 21 CFR 801 Subpart D) **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)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K082968