3/19/99 K983572

1. 510(k) SUMMARY

(As required by 21 CFR 807.93)

Establishment Registration Number: 1040777

Submitter:
Betsy Cortelloni
Respironics, Inc.
1255 Kennestone Circle
Marietta, GA 30066
Phone: 770-429-2894
Fax: 770-499-1139

Name of Contact: Betsy Cortelloni, Regulatory Affairs Process Leader

Device Name: Simon™ Multichannel Recording System

Device Model Number: 5500

Classification Name: Programmable Diagnostic Computer, 21 CFR 870.1425

Device Classification: DQK

Predicate Devices: Healthdyne Technologies' Alice 4 System. Originally cleared under K971867 (8/13/97).

Device Description: Simon™ is a multichannel recording system, which may be used for adult or pediatric patients in a variety of settings. The system is comprised of the Simon Recorder, Host Software, auxiliary CPAP / BiPAP devices (as applicable), computer equipment (CPU and monitor) and various accessories (modem, etc.). The recorder is small, lightweight and may be worn while the patient sleeps. The recorder collects physiologic signals from sensors attached to the patient. This eight-channel system records Nasal Flow or Pressure, Body Position, Snoring Sounds, Oximetry, Respiration via Chest Effort, Respiration via Abdominal Effort, Actigraphy, Pressure and Flow from auxiliary Respironics CPAP / BiPAP devices.

The Simon™ Host Software is a Windows-based application, which facilitates remote titration of CPAP / BiPAP settings via modem, as well as download of recorded data onto a personal computer. Once downloaded, the Host software scores the recorded data for physiological events per user-defined parameters.

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510(K) SUMMARY – SIMON™ MULTICHANNEL RECORDING SYSTEM
Device Description, continued:

The software allows user validation/editing of all events, and provides reporting capabilities that are fully user-configurable.

Intended Use:

Simon™ is a multichannel recording system designed to record and store physiological signals acquired from adult and pediatric patients during sleep. The portable design of the device facilitates its use in any clinical setting or in the home environment.

Physiological signals are acquired via transducers attached to the patient and directly connected to the recorder. Additionally, a modem may be used to connect to the Host PC during acquisition, to interface with a Respironics CPAP or BiPAP device for titration or to download the data post acquisition. Once downloaded, the recorded data can be scored for physiological events using the associated Simon™ HOST Software.

The clinician can review, validate, edit and print scored data. The software allows the user to configure / customize all reports to best meet individual needs.

Comparison of Technological Characteristics:

Simon™ is essentially a line extension of the Healthdyne Technologies Alice 4 System and utilizes the same software "engine" to control device functions. Simon records eight input channels and will display ten, as compared to 20 channels on Alice 4. Signals are recorded in a similar manner.

Simon™ is designed to facilitate home use although it may also be used in clinical settings. It is small and lightweight enough to be worn by the patient as s/he sleeps. It is operated using a wall mounted power supply or a rechargeable battery back.

The Simon™ Host Software facilitates download of recorded data to a PC via external modem or direct connection to the device.

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510(K) SUMMARY – SIMON™ MULTICHANNEL RECORDING SYSTEM

Testing: The System Qualification Test Plan for Simon™ included Operational and Performance testing, Environmental testing and EMC testing. The Hardware Test Plan and Software Test Plan consisted of system level and module / integration level testing to verify all the defined hardware and software requirements, respectively. Bench testing utilized simulated data. No Clinical testing was performed.

Conclusion: The cumulative test results demonstrated the functionality, safety and effectiveness of the Simon™ Multichannel Recording System, 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

MAR 19 1999

Ms. Betsy Cortelloni
Healthdyne Technologies
1255 Kennestone Circle
Marietta, GA 30066-6029

Re: K983572
Simon Multichannel Recording System
Regulatory Class: II (two)
Product Code: 73 MNR
Dated: February 8, 1999
Received: February 9, 1999

Dear Ms. Cortelloni:

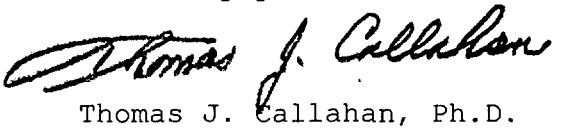
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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"(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/dsma/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): K983572

Device Name: SIMON MULTICHANNEL RECORDING SYSTEM

Indications for Use:

Simon™ is a multichannel recording system designed to record and store physiological signals acquired from adult and pediatric patients during sleep. The portable design of the device facilitates its use in any clinical setting or in the home environment.

Physiological signals are acquired via transducers attached to the patient and directly connected to the recorder. Additionally, a modem may be used to connect to the Host PC during acquisition, to interface with a Respironics CPAP or BiPAP device for titration or to download the data post acquisition. Once downloaded, the recorded data can be scored for physiological events using the associated Simon™ HOST Software.

The clinician can review, validate, edit and print scored data. The software allows the user to configure / customize all reports to best meet individual needs.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurence of CDRH, Office of Device Evaulation (ODE)

Ruth A. Gardner

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number _____

✓ prescription use