4/19/99

K990199

RESPIRONICS®

1255 Kennestone Circle
Marietta, Georgia
30066-6029 USA

SMARTRECORDER™ MULTICHANNEL RECORDING SYSTEM

510(k) SUMMARY

(As required by 21 CFR 807.93)

Establishment Registration Number:	1040777
Submitter:	Betsy Cortelloni Respironics Georgia 1255 Kennestone Circle Marietta, GA 30066 Phone: 770-429-2894 Fax: 770-499-1418
Name of Contact:	Betsy Cortelloni, Regulatory Affairs Manager
Device Name:	SmartRecorder Multichannel Recording System
Device Model Number:	2500
Classification Name:	Programmable Diagnostic Computer, 21 CFR 870.1425
Device Classification:	**DQK**
Predicate Devices:	Healthdyne Technologies' Alice 4 System, K971867. Masimo SET MS-1 Pulse Oximeter and Accessories, K962603. Simon Multichannel Recording System, K983572.
Device Description:	SmartRecorder™ is a software-controlled device, which utilizes the same "engine" as Healthdyne Technologies' Alice®4 Sleep Diagnostic system. SmartRecorder is a scaled down version of Alice 4, having fewer channels and weighing less than three pounds. SmartRecorder acquires, records and stores up to seven dedicated channels of sensor-input physiologic data, and provides the capability to interface with Respironics infant monitoring devices and sleep therapy devices to record ECG and respiration signals, or pressure and flow signals, respectively. Additionally, SmartRecorder acquires analog data through four auxiliary channels. SmartRecorder includes built-in Masimo SET® oximetry technology.

The acquired data is recorded and stored in non-volatile removable PCMCIA flash memory, and can be retrieved by direct PC connection; remotely via internal modem; or by transferring the data directly from the memory card to a PC.

A graphic LCD display provides feedback and instruction to the clinician to assist in setup of a patient.

The associated Host software, Synergy S™, allows the HealthCare Professional (user) to access the stored data for subsequent validation and editing of all events, and provides reporting capabilities that are fully user-configurable. Synergy S is a Windows-based application, which also facilitates remote titration of CPAP / BiPAP settings via modem.

Intended Use:

The Respironics SmartRecorder is a multichannel recording system designed to record and store physiologic signals acquired from adult and infant patients during sleep. SmartRecorder is designed for use in the home or hospital.

Physiological signals are acquired via transducers attached to the patient and directly connected to the recorder and/or monitoring or therapeutic device connected to the recorder.

Use of the associated Synergy S (host) software facilitates retrieval of data recorded by SmartRecorder via direct PC connection; remotely via internal modem; or by transferring data directly from the removable PCMCIA memory card to a PC. Once downloaded, the recorded data can be analyzed for physiological events.

Synergy S allows the clinician can display, review, edit and print analyzed data as well as configure / customize all reports to best meet individual needs.

Comparison of Technological Characteristics:

SmartRecorder is essentially a line extension of the Healthdyne Technologies Alice 4 System and utilizes the same software "engine" to control device functions. SmartRecorder records seven sensor-input channels and four auxiliary channels, as compared to 20 channels on Alice 4. Signals are recorded in a similar manner.

SmartRecorder is small and lightweight, and is designed for home or hospital use. It is operated using a wall mounted power supply.

The Synergy Software facilitates download of recorded data to a PC via internal modem or direct connection to the device.

510(K) SUMMARY – SMARTRECORDER™ MULTICHANNEL RECORDING SYSTEM Continued:

Testing: The System Qualification Test Plan for SmartRecorder 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 SmartRecorder Multichannel Recording System and the associated Synergy Software, as well as their substantial equivalence to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 19 1999

Ms. Betsy Cortelloni
Respironics, Inc.
1255 Kennestone Circle
Marietta, GA 30066

Re: K990199
Smartrecorder, Model 2500
Regulatory Class: II (two)
Product Code: 73 MNR
Dated: January 19, 1999
Received: January 21, 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

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): K990199

Device Name: SMARTRECORDER MULTICHANNEL RECORDING SYSTEM

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A. Hall.

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number _____

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Concurence of CDRH, Office of Device Evaulation (ODE)

PRESCRIPTION USE X OR OVER-THE-COUNTER USE _____