K011597

JAN 11 2002

RESPIRONICS
www.respironics.com

510(k) SUMMARY OF SAFETY & EFFECTIVENESS
SMARTMONITOR 2 INFANT APNEA MONITOR / SYNERGY-E SOFTWARE

Establishment Registration Number: 1040777

Official Contact:
Betsy Cortelloni
Respironics Georgia, Inc.
175 Chastain Meadows Court
Kennesaw, GA 30144
Phone: 770-429-2894
Fax: 770-423-2309

Name of Contact: Betsy Cortelloni, Regulatory Affairs Manager

Device Name: SmartMonitor 2 / Synergy-E

Device Model Number: 4000 Series

Classification Name: Apnea Monitor, 21 CFR 868.2377

Device Classification: Class II (Special Controls)

Predicate Devices: Healthdyne Technologies SmartMonitor. Originally cleared under K892006 (5/23/89).

Device Description: The SmartMonitor 2 is a monitoring device designed to monitor respiration and heart rate. Upon detection of abnormal events, SmartMonitor 2 alerts the caregiver via both visual and audible alarms and records the information for subsequent clinical review.

SmartMonitor 2 acquires the electrical activity of the heart via a two or three-lead electrode configuration. The same set of electrodes is used to measure transthoracic impedance and to subsequently develop a respiration signal. Detection of heart beats and respiration breaths is accomplished via software-based algorithms, which analyze the ECG and respiration signals. When beats or breaths are detected, SmartMonitor 2 provides feedback by blinking the Heart and Respiration LED's and calculates apnea intervals, average heart rates, and average breath rates for the purpose for identifying ECG and respiration rates that violate preset threshold values. In addition to the alarms, when abnormal ECG and respiration rates are detected, both tabular data and associated waveforms are logged in non-volatile memory for subsequent review by a Health Care Professional.

510(k) Summary, continued:

Intended Use: The SmartMonitor 2 Infant Apnea Monitor is intended for use in the continuous monitoring of respiration and heart rate of infant patients in a home or hospital environment. The monitor detects and alarms for periods of central apnea and high or low heart rates.

Comparison of Technological Characteristics: The SmartMonitor 2 is functionally equivalent to the original SmartMonitor. Many of the differences that exist are not readily visible to the user. Primary differences are:

- SmartMonitor 2 is available with an internal modem and/or a removable PCMCIA memory card;
- Enhanced menu options;
- SmartMonitor 2 powers down in less than 1 second; and
- SmartMonitor 2 can download memory (2 Mbytes) in approximately three minutes.

The performance specifications of SmartMonitor and SmartMonitor 2 for **Respiration** monitoring are:

• Resp. Detection Rate	1 to 120 BrPM @ 1Ohm, peak to peak
• Sensitivity	0.1 to 5 Ohms, peak to peak
• Output Amplitude Accuracy	+/- 5%
• CMRR	>75 dB at 60 Hz
• Input Impedance	> 75 KOhms
• Detection amplitude range	0.2 to 5 Ohms, peak to peak

The performance specifications of SmartMonitor and SmartMonitor 2 for **ECG** monitoring are:

• ECG Detection Rate	25 to 300 BPM @ 1mV, baseline to peak
• Sensitivity	+/- 0.1 to +/- 5.0 mV
• Output Amplitude Accuracy	+/- 2%
• ECG CMRR	> 75 dB at 60 Hz
• Input Impedance	> 75 KOhms
• Detection Amplitude Range	0.2 mV to 5 mV, baseline to peak

RESPIRONICS
www.respironics.com

510(k) Summary, continued:

Testing:

Performance

System qualification testing of the SmartMonitor 2 was conducted in accordance with internal Respironics procedures as well as applicable standards and guidances including, but not limited to, the draft apnea monitor performance standard formerly found in 21 CFR Part 896, ANSI/AAMI EC13, and IEC 601-1.

The results of these tests support that the SmartMonitor 2 meets the requirements specified in the Product Specification and that it conforms to the required standards.

Software

Testing for the firmware and host software consisted of system level testing, software requirements testing, and module/integration level testing. Test results confirmed that all requirements were met.

Clinical

The clinical protocol was designed to compare the performance of SmartMonitor 2 to the predicate SmartMonitor. Data were compiled from multiple sites on at risk infants, and verified via the "gold standard" of hand scoring.

Data were analyzed as specified in the *Guidance for Apnea Monitor 510(k) Submissions, released 2002.* The results confirmed the substantial equivalence of the SmartMonitor 2 to the predicate SmartMonitor in detection of central apnea.

Conclusion:

The results of the performance and clinical testing demonstrated the functionality, safety and effectiveness of the SmartMonitor 2 Infant Apnea Monitor, as well as its substantial equivalence to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 11 2002

Ms. Betsy Cortelloni
Regulatory Affairs Manager
Respironics Georgia, Inc.
175 Chastain Meadows Court
Kennesaw, GA 30144

Re: K011597
SmartMonitor® 2, Model 4000
Regulation Number: 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: Class II (two)
Product Code: FLS
Dated: October 12, 2001
Received: October 15, 2001

Dear Ms. Cortelloni:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,

Bram D. Zuckerman, M.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Center of Devices and Radiological Health

510(k) Number (if known): K011597

Device Name: SMARTMONITOR 2

Indications for Use:

The SmartMonitor® 2 Infant Apnea Monitor is intended for use in the continuous monitoring of respiration and heart rate of infant patients in a home or hospital environment. The monitor detects and alarms for periods of central apnea and high or low heart rates.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of [illegible] & Dental Devices
510(k) K011597

✓ Prescription Use