MAY 14 1998

SECTION 1

SUMMARY OF SAFETY & EFFECTIVENESS

RESPIRONICS INC.®
1001 Murry Ridge Drive, Murrysville, PA 15668

Official Contact	Raj S. Kasbekar Engineer, Regulatory Affairs Respironics, Inc. 1001 Murry Ridge Drive Murrysville, PA 15668
Classification Reference	21 CFR 870.2700
Common/Usual Name	pulse oximeter
Proprietary Name	Stardust
Internal Project Name	One Night Stand (ONS)
Predicate Devices	HMS 4000 (K914620/A) Respironics, Inc. 1001 Murry Ridge Drive Murrysville, PA 15668 HMS 5000 (K914085) Respironics, Inc. 1001 Murry Ridge Drive Murrysville, PA 15668
Reason for submission	New Device

Substantial Equivalence

This premarket notification section 510(k) submission demonstrates that the Stardust is substantially equivalent to the Respironics HMS 4000 (K914620/A) and the Respironics HMS 5000 (K914085), all of which have the same intended use.

Testing was performed to demonstrate that the performance of the Stardust in its intended environment is as safe and effective as that of the legally marketed predicate devices. The safety and effectiveness of Stardust were verified through performance-related testing that consisted of Electrical Safety, Electromagnetic Compatibility, Mechanical and Environmental Testing. The Stardust was tested and found compliant with the standards referenced in the "Draft FDA Reviewer Guidance for Premarket Notifications," November 1993.

Device Description/Intended Use

A low-power, diagnostic, recording device that interfaces with predefined sensors, and processes and records physiologic patient data.

The Stardust is a respiratory disorder diagnostic device that is intended to be used to measure and record five parameters. These parameters are:

- ❑ percent SpO_2 (functional)
- ❑ pulse rate
- ❑ oral/nasal airflow
- ❑ respiratory effort
- ❑ body position (i.e., supine or non-supine)

It can also be connected to a Respironics Virtuoso Smart CPAP System to record and display continuous positive airway pressure (CPAP) and airway index level. The Stardust can be used as a stand alone unit for recording data. It also interfaces with a commercially available IEC 950 compliant computer and can be used to view data real-time in a recording or non-recording mode. The Stardust does not have any audible alarms and, therefore, should not be used for continuous monitoring.

Software

The pulse oximetry data, raw infrared and red waveform data, pulse rate data, airflow data, respiratory effort data and position data can be viewed real-time on a computer using Respironics' custom Windows™-based software that is provided with the Stardust. The software also enables the clinician to do some data analysis, which can be used to draw meaningful implications during sleep apnea analysis.

Indications for Use

The Stardust is indicated for use in the diagnosis of respiratory disorders, such as sleep apnea.

Environment of Use/Patient Population

The Stardust is intended for the hospital/institutional environment (supervised) and the home (unsupervised) environment for patients weighing more than 30 kg. It is not intended for use with infants.

Contraindications:

- The pulse oximeter module of the Stardust is not intended for use during magnetic resonance imaging (MRI) procedures or in an MRI environment.
- As with any pulse oximeter, the pulse oximeter module of the Stardust is not intended for use on patients, such as heavy smokers, with high carbon monoxide (CO) blood content.
- The pulse oximeter module of the Stardust is not intended for use in any application requiring fractional saturation measurements.
- The pulse oximeter module of the Stardust is not intended for use as an apnea monitor.

Stardust Accessories

The Stardust can be used with the following accessories:

- EPM Infinity Reusable Airflow Sensor (K922112A)
- Bionique Reusable Thermistor Assembly (K912427)
- EPM Resp-Ez Respiratory Effort Sensor (K903300A)
- ~~Critticare Finger Probe (Clip) (K961223)~~ UDT
- Windows Diagnostic Software (proprietary name: SleepWare)
- RS232 cable
- RS232 adapter box

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 14 1998

Mr. Raj S. Kasbekar
Respironics, Inc.
1001 Murry Ridge Drive
Murrysville, PA 15668-8550

Re: K973920
Stardust
Regulatory Class: II (two)
Product Code: 73 MNR
Dated: February 13, 1998
Received: February 13, 1998

Dear Mr. Kasbekar:

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 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/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): K973920

Device Name: Stardust

Intended Use/Indications for Use

Intended Use:

The Stardust is a respiratory disorder diagnostic device that is intended to measure and record five parameters. These parameters are percent SpO_2 (functional), pulse rate, oral/nasal airflow, respiratory effort, and body position (i.e., supine or non-supine). It can also be connected to a Respironics Virtuoso Smart CPAP System to record and display continuous positive airway pressure (CPAP) and airway index level.

The Stardust can be used as a stand-alone unit for recording data. It also interfaces with a commercially available IEC 950 compliant computer, which enables you to view data real-time in a recording or non-recording mode. The Stardust does not have any audible alarms and, therefore, should not be used for continuous monitoring of oxygen saturation or as a replacement for pulse oximeter monitors.

Software

The pulse oximetry data, raw infrared and red waveform data, pulse rate data, airflow data, respiratory effort data and position data can be viewed real-time on the computer using Respironics' custom Windows™-based software (SleepWare) provided with the Stardust. The software also enables the clinician to do some data analysis, which can be used to draw meaningful implications during sleep apnea analysis.*

Indications for Use: The Stardust is indicated for use in the diagnosis of respiratory disorders, such as sleep apnea.

Environment of Use/Patient Population:

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- The pulse oximeter module of the Stardust is not intended for use as an apnea monitor.

* The software also enables the user to

- Create, edit, delete and print patient information
- View waveform recordings/ table data
- Edit waveform recordings
- Set event, bad, and wake markers
- Perform data analysis using manual or auto-scoring (see below)
- Print results graphically
- Set the recorder's internal real-time clock

- Clear the recorder's memory
- Generate a patient report
- Display status, session #, battery voltage, memory usage

Manual scoring lets the operator view the waveform recording , look at specific events and determine the event (type of apnea or hypopnea using his/her own judgement) based on the waveform or event parameters.

Automatic scoring classifies the event for a region of data or for the entire recording and using certain rules automatically displays the event type (type of apnea or hypopnea) on the screen. The rules for scoring can be set by the operator in terms of start parameters (parameters used to start the apnea or hypopnea such as minimum event duration and peak inspiratory value) and termination parameters(parameters used to terminate the apnea or hypopnea such as maximum event duration, peak inspiratory value, number of breaths to terminate event and maximum time between breaths).

For example,

1) If the start parameters for **apnea** are set as

Minimum event duration	10 seconds
Peak Inspiratory Value to start an event	20% of local IRA,

then the scoring algorithm will classify any breath event with amplitude below 20% and with a minimum event duration of 10 seconds as an apnea.

2) If the start parameters for **hypopnea** are set as

Minimum event duration	10 seconds
Peak Inspiratory Value to start an event	66%,

then the scoring algorithm will classify any breath event with amplitude below 66% and with a minimum event duration of 10 seconds as hypopnea.

3) If the termination parameters for apnea are set as

Maximum event duration	5 min
Peak Inspiratory Value to end an event	40% of local IRA
Number of breaths to terminate an event	1
Maximum Time between Breaths	10 seconds,

then the scoring algorithm will stop the apnea classification whenever it encounters a duration of 5 minutes with the breath amplitude above 40% of the local IRA.

4) If the termination parameters for apnea are set as

Maximum event duration	5 min
Peak Inspiratory Value to end an event	80% of local IRA
Number of breaths to terminate an event	1
Maximum Time between Breaths	10 seconds,

then the scoring algorithm will stop the hypopnea classification whenever it encounters a duration of 5 minutes with the breath amplitude above 80% of the local IRA.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use

(Per 21 CFR 801.109) (Optional Format 1-2-96)

Thomas J. Callahan

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K973920