K 040595

MAR 1 8 2004

Date of Submission	11 February 2004
Official Contact / Address of Manufacturing facility	Zita A. Yurko Manager, Regulatory Affairs Respironics Inc. 1001 Murry Ridge Lane Murrysville, PA 15668 Phone: 724-387-4120 Fax: 724-387-4216 Zita.yurko@respironics.com
Proprietary Name	Alice 5 System
Common/Usual Name	Electroencephalograph/Polysomnography System
Device Classification Name	Electroencephalograph/Polysomnography System
Classification Reference	21 CFR 882.1400
Classification	Class II
Appropriate Classification Panel	Neurology
Product Code	OLZ, OLV
Predicate Devices	Respironics Alice 4R (K971867) Masimo SET Oximeter (K990966) Devilbiss Sleep Recorder (K012437)
Reason for submission	Modified design

Substantial Equivalence

This premarket notification submission demonstrates that the Alice 5 system is substantially equivalent to a combination of the Respironics Alice 4R (K971867), Masimo SET Oximeter (K990966), and the Devilbiss Sleep Recorder (K012437).

The design of the Alice 5 was verified through the use of design verification and validation testing. The Hazards Control Measures Traceability Matrix provided in the Risk Analysis assured that all hazards identified by the risk analysis were successfully mitigated.

This submission is seeking to extend the existing claims of the Alice system to include additional channels to process and record physiologic information.

Indications for Use

The Alice 5 System is a Polysomnography System that is intended to record, display and print physiological information to clinicians/physicians. These parameters are presented graphically on a computer screen for diagnostic review, similar in application to the use of a traditional paper based polygraph recorder. The device will be used in hospitals, institutions, sleep centers or clinics, or other test environments where adults or infant patients require the documentation of various sleep or other physiological disorders.

This device does not provide alarms and, is not intended for use as an automated apnea monitor.

Device Description

The Alice 5 is a multi-functional recording device. The system is used for the recording, monitoring, storage and transfer of up to 55 channels of biophysical parameters such as brain, heart and muscle activity, eye movement, blood pressure, breathing, body movements and oximetry. In addition it has 5 auxiliary channels and 2 serial channels for connection of external devices.

Electrodes and sensors from the patient are connected to Alice 5 head box which in turn is connected to the Alice 5 base station (recording unit) for data processing and recording.

Patient studies recorded using the Alice 5 head box and the base station are viewed, printed, summarized, and analyzed using the Alice Sleepware Software.

Technological characteristics, comparison to predicate devices

Like the predicate devices, the Alice 5 system is intended to detect physiological signals from various points on the patient's body, individually or as a signal measured between selected electrodes and to record those signals in accordance with preset parameters (in a montage) for analysis by a clinician.

Characteristic	Alice 4R (K97xx)	Devilbiss Sleep Recorder, Model RM60 (K012437)	Alice 5
Intended Use	The Alice 4 System is a polysomnography system that is intended to record, display and print EEG and other physiological information to clinicians/physicians. The device will be used in hospitals, institutions, sleep centers or clinics or other test environments where adult or infant patients require the documentation of various sleep or other physiological disorders.	The Devilbiss Sleep Recorder is intended for screening patients suspected of or exhibiting symptoms of sleep disorders. The Devilbiss Sleep Recorder can be used with an autotitrating CPAP to record the results of CPAP treatment for adults diagnosed with sleep apnea syndrome. Patients suffering from excessive daytime sleepiness should be referred to a sleep disorder specialist. The results of an unattended screening are insufficient to identify all possible medical disorders that may product these symptoms. This device is intended to aid the physician in diagnosing adult sleep apnea. A qualified medical professional should score the device's recorded signals to determine respiratory events. The Devilbiss Sleep Recorder or any of its components should not be used as a life support device, life support system, or as a critical component of a life support device or life support system.	The Alice 5 System is a Polysomnographic System that is intended to record, display and print physiological information to clinicians/physicians. These parameters are presented graphically on a computer screen for diagnostic review, similar in application to the use of a traditional paper based polygraph recorder. The device will be used in hospitals, institutions, sleep centers or clinics, or other test environments where adults or infant patients require the documentation of various sleep or other physiological disorders. This device does not provide alarms and, is not intended for use as an automated apnea monitor.
Configuration	Desktop	Wearable	Desktop
Number of patients can monitor simultaneously	1 per unit	Same	Same
Portable Design	Yes	Same	Same
Data Collection	Yes	Yes	Yes
Data Analysis	Optional (always present, but a clinician may choose to use it or not)	Optional	Optional (always present, but a clinician may choose to use it or not)
Report Generation	Optional (always present, but a clinician may choose to use it or not)	Optional	Optional (always present, but a clinician may choose to use it or not)
Capable of Data Transfer for Analysis and Report Generation	Yes	Yes	Yes

Channels	35	9	51
Data input types	ECG, Neurological, Respiratory	ECG, respiratory	ECG, Neurological, Respiratory
Remote Capability to Monitor Lead Quality	Yes	Yes	Yes
Electrode Impedance check	Yes	Yes	Yes
Calibration Check	Yes	Yes	Yes
Selectable Montage Configuration	Yes	Yes	Yes
Annotations on study	Yes	Yes	Yes
Raw data storage	Yes, Hard Disk	Yes, Flash	Yes, Hard Disk
Study Modes	Polysomnography Recording Long term Monitoring, Retrieval and Replay	Overnight at-home study	Polysomnography Recording Long term Monitoring, Retrieval and Replay
Optional equipment	Time Sync Video, Digital video, printer	Not Available	Digital video, printer
Radio LAN Capabilities	No	No	Yes

Performance testing

An extensive collection of tests has been conducted and successfully completed, including safety, performance and comparative tests. Declarations of conformance to the FDA Recognized list of consensus standards, as well as FDA reviewers guidance and Applicable voluntary standards have been provided in support of the safety and effectiveness of the Alice 5 System. This list of performance testing included in the submittal is as follows:

- IEC 60601-1: 1988 + A1: 1991 + A2: 1995, Medical Electrical Equipment – Part 1: General Requirements for Safety - Tab 11A
- IEC 60601-1-2: 2001 Medical Electrical Equipment Part 1-2: Collateral Standard: Electromagnetic Compatibility – Requirements and tests – Tab 11B
- ISO-10993-1: Biological Evaluation of Medical Devices – Evaluation and Testing – Tab 9

- FDA Reviewer's Guidance (#G95-1, 5/1/95) Biological Evaluation of Medical Devices; Use of ISO-10993 – Tab 9
- Alice 4R to Alice 5 Bench test comparison report; assesses the event (breath) detection capability of the Alice 4R vs. Alice 5 and the autoscoring algorithm. For this testing a known set of inputs (depicting apneas/hypopneas) was simulated as an input to the Alice 4R and the Alice 5.
- Devilbiss Sleep Recorder Pulse Transit Time vs. the Alice 5 PTT waveform recording assessment to determine equivalence in the PTT measurement between the Alice 5 and the Devilbiss Sleep Recorder.
- Devilbiss Sleep Recorder Snore channel/signal to the Alice 5 Snore recording assessment to determine equivalence in the data collection and waveform presentation between the Alice 5 and the Devilbiss Sleep Recorder.
- Devilbiss Sleep Recorder Pressure Based Flow channel/signal to the Alice 5 Pressure Based Flow waveform recording assessment to determine equivalence in the data collection and waveform presentation between the Alice 5 and the Devilbiss Sleep Recorder.
- Alice 4R vs Alice 5 thermistor channel/signal comparison to determine equivalence in the data collection and waveform presentation between the Alice 4R and the Alice 5 systems.
- Alice 5 System Requirements Test Procedure/Report; assesses the features of the Alice 5 to ensure compliance with the System level requirements.
- Alice 5 Shock & Vibration Test Report; assesses compliance of the Alice 5 system to the IEC 68-2-34, & 2-26 standards.
- Alice 5 Temperature & Humidity Report; assesses compliance of the Alice 5 Head Box and base Station to the Operational and Storage test conditions stated in the 1993 FDA Reviewers Guidance.

Additional testing has been performed in to ensure safety & effectiveness of the Alice 5 System. This testing involves the unit, module, and functional testing of the software of the device (firmware) and the Alice Sleepware Software. Since we are able to declare compliance to AAMI: SW68:2001 Medical Device software – Software life cycle processes, these test protocols and reports are not required to be submitted as part of this submittal, but are available upon request. Additionally the following set of standards and guidance documents have been used in the design of the Alice 5 System. These include:

Required Standards – A Declaration of Conformity for each of these standards is provided in the submittal:

- ANSI/AAMI SW68: 2001 Medical Device Software – Software Life Cycle Processes.
- IEC 60601-1: 1988 + A1: 1991 + A2: 1995, Medical Electrical Equipment – Part 1: General Requirements for Safety
- IEC 60601-1-2: 2001 Medical Electrical Equipment Part 1-2: Collateral Standard: Electromagnetic Compatibility – Requirements and tests
- ISO-10993-1: Biological Evaluation of Medical Devices – Evaluation and Testing

Voluntary Standards - Guidance, when applicable, has been adopted from the following standards.

- IEC 60601-2-25: 1993 + A1: 1999 Medical Electrical Equipment – Part 2-25: Particular requirements for the safety of electrocardiographs.
- IEC 60601-2-26: 2002 Medical Electrical Equipment – Part 2-26: Particular requirements for the safety of electroencephalographs.
- IEC 60601-2-40: 1998 Medical Electrical Equipment – Part 2-40: Particular requirements for the safety of electromyographs and evoked response equipment.
- IEC 60601-2-49: 2001 Medical Electrical Equipment – Part 2-49: Particular requirements for the safety of multifunction patient monitoring equipment.

Reviewers Guidance - Guidance, when applicable, has been adopted from each of the FDA Reviewers Guidance documents

- FDA Guidance Document, Electroencephalograph Devices Guidance for 510(k) Content, Draft Document, Version 1.0.
- FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, May 1998
- FDA Reviewer's Guidance (#G95-1, 5/1/95) Biological Evaluation of Medical Devices; Use of ISO-10993
- FDA Reviewer's Guidance for Premarket Notification Submissions, Appendix A, November 1993
- FDA Reviewer's Guidance General Principles of Software Validation; Final Guidance for Industry and FDA Staff, January 2002

Conclusion

It is the conclusion of Respironics that the Alice 5 system is substantially equivalent to devices already on the market (cleared by the 510(k) process) and presents no new concerns about safety and effectiveness.

(End of Tab.)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Respironics, Inc.
c/o Mr. Ned E. Devine, Jr.
Entela, Inc.
3033 Madison Avenue, SE
Grand Rapids, Michigan 49548

Re: K040595
Trade/Device Name: Alice 5 System
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: II
Product Code: OLZ, OLV
Dated (Date on orig SE ltr): March 3, 2007
Received (Date on orig SE ltr): March 8, 2004

APR - 9 2012

Dear Mr. Devine:

This letter corrects our substantially equivalent letter of March 18, 2004.

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Keoia Alexander

for

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K040595

Device Name: Alice 5 System

Indications for Use:

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K040595