K052489

TAB 10

SEP 2 7 2005

510(K) SUMMARY

Date of Submission	June 15, 2005
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	Actiheart
Common/Usual Name	Heart Rate Monitor
Device Classification Name	Physiological Signal Recorder
Classification Reference	21 CFR 882.1845
Classification	Class II
Appropriate Classification Panel	Neurology
Product Code	GWK
Predicate Devices	Mini Logger Series 2000 (Mini Mitter Co., Inc.)
Reason for submission	New device

Substantial Equivalence

This premarket notification submission demonstrates that the Actiheart system is substantially equivalent to the Mini Logger Series 2000 (K991045).

The design of the Actiheart 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 obtain clearance to market a new product that is substantially equivalent to the Mini Logger Series 2000. The new product (Actiheart) performs substantially equivalent measurements of Heart Rate and Activity as the Mini Logger Series 2000.

Indications for Use

The *Actiheart* is an ambulatory Heart Rate and Activity Recorder. *Actiheart* may be used to quantifiably measure Heart Rate, Activity, and estimates of Caloric Expenditure. This device is not intended for use as an ECG monitor.

Device Description

Actiheart is a compact, ambulatory, physiological Heart Rate and Activity data recorder. *Actiheart* may be attached to the chest surface through the use of standard ECG electrodes. Recorded data may be transferred later to a PC for display and conversion for export to other programs.

Basic scientific concepts

The device acquires and logs digital data whose values represent the rate of Heart Beat (BPM), based on a proprietary analysis of ECG complexes. (*Actiheart* is not an ECG monitor.) The scientific concepts and technologies that are used to sense the signals are summarized in Table 10A.

TABLE 10A. BASIC TECHNOLOGIES USED FOR PHYSIOLOGICAL SIGNAL RECORDING IN *ACTIHEART* RECORDERS

Physiological Parameter	Where Obtained	Technology	Value Obtained
Heart Rate	*Actiheart*	Differential amplifier senses and amplifies ECG signal. Proprietary code transforms digitized signal and detects location of features in ECG complex.	Digital value corresponding to heart Beats Per Minute (BPM).
Activity	*Actiheart*	Signal from accelerometer amplifier is digitized and analyzed using proprietary algorithms to detect motion.	Digital value corresponding to Activity Counts
Caloric Expenditure (derived)	*Software*	Conversion of Activity Counts and HR to corresponding value of Calories Expended (proprietary algorithm)	Value corresponding to Calories Expended

Physical characteristics of Actiheart

Pertinent physical characteristics of the *Actiheart* are shown in Table 10B.

TABLE 10B. PHYSICAL CHARACTERISTICS OF *ACTIHEART* RECORDER

Parameter	Value	Condition/Note
Size	195mm length, overall 38mm diameter 12.5mm tail clip	Outer dimensions
Weight	12 grams	With no ECG electrodes attached
Case material	Polycarbonate/ABS	Flammability rating UL94 V-0
Attachment clip material	Stainless steel	
Attachment type	Adult ECG snap	
Battery type	3.0 volt lithium rechargeable	Not user replaceable
Indicators	Green LED	Coincident with heart beat

Functional Description

Actiheart is intended for the measurement, storage, and display of physiological data (Heart Rate (HR) and Activity (ACT)). In addition, Actiheart derives an approximate value of Energy Expenditure from the values of HR and ACT. Actiheart can be attached to the subject's chest using standard ECG electrodes. Through the use of various types of standard ECG electrodes, the Recorder may be worn for varying lengths of time, dependent on the amount of data logging desired and the recommendations of the ECG electrode manufacturer. Parameter data are logged on board the Recorder and later transferred through a cable to a personal computer via the Reader. The PC Software can be used to display the physiological data and store the data for future comparison. The Multicharger is used to re-charge the Recorder's on-board rechargeable lithium battery.

Technological characteristics, comparison to predicate device

Actiheart and the Mini-Logger Series 2000 Heart Rate Probe (K991045) are each diagnostic test systems based upon the concept of an ambulatory, unattended physiological recorder that logs physiological data to the logging device. Each of these devices is a solid-state Recorder with differential amplifiers, data collection and analysis algorithms, and with the ability to store data until it is transfered into the PC. Actiheart and the Mini-Logger Series 2000 Heart Rate Probe are of similar size and weight. Both devices measure and record Heart Rate and Activity.

The physiological data logging device presented in this 510(k) submission (*Actiheart*) is substantially equivalent to the *Heart Rate Probe* currently marketed as part of the *Mini-Logger® Series 2000 Physiological Data Logging Device* (K991045).

The *Actiheart* and the *Mini-Logger® Series 2000 Heart Rate Probe* are of similar size and weight. Both devices have the ability to measure Heart Rate. Both devices are surface-mounting, chest-worn, and ambulatory.

The performance characteristics are illustrative of comparable devices. Similarities and differences between *Actiheart* and the predicate device are presented below in Table 10C. Where differences exist, they reflect reduced indications for use and improvements in convenience of use.

TABLE 10C. SUBSTANTIAL EQUIVALENCE COMPARISON

COMPARISON PARAMETER	*Actiheart*	*Mini-Logger® Series 2000 with Heart Rate Probe* (K991045)
Device description	Compact, wearable, battery-operated physiological *data recorder*	Compact, wearable, battery-operated physiological *data recorder*
Where used	*Actiheart* may be used where quantifiable measurement of human Heart Rate and/or Activity is needed. It may be used in the home or hospital environments	The *Mini-Logger®* may be used in any instance where quantifiable analysis of physiological data is desirable. It may be used in the home or hospital environments
Visual appearance and physical description of Recorder/probe	195mm length 38mm diameter 12.5mm tail clip	145 mm length 31 mm wide
HR channels	1	1
Materials (Recorder)	Polycarbonate/ABS plastic case	ABS plastic case
Mode of operation (Recorder)	Recorder input	Wireless Recorder input and Direct-wired Recorder input
Design features (System)	Maximum recording time 14 days	Maximum recording time 88 days
Memory (system)	1 Megabit	128 Kilobyte or 1 Megabyte
Performance	Comparable (see included)	Comparable (see included)
Heart Rate range	35 to 255 BPM	Up to 250 BPM
Heart Rate resolution	1 BPM	1 BPM
Heart Rate accuracy*	±10% of value, not to exceed 5 BPM (Meets EC-13-4.2.7)	Unpublished
R-wave detection	dv/dt with variable threshold, sampling at 128 Hz	Performed by the heart rate probe. Method is unpublished.
Sterility (Recorder)	None required	None required
Biocompatibility (Recorder)	Through the use of ECG electrodes	Through the use of ECG electrodes
Human factors (Recorder)	Attaches to ECG electrodes	Waist pack carrying case, direct-wire attachment to ECG electrodes, or telemetric link

Electrical safety (Recorder)	Battery operated	Battery operated
Power used (Recorder)	3.0 volt rechargeable lithium battery (1 each)	3.6 volt disposal lithium battery (2 each)

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 Actiheart System. This list of performance testing included/will include:

- 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
- Actiheart to Mini Logger Series 2000 bench test comparison report; assesses the Heart Rate detection performance characteristics of both devices side-by-side against a set of library recordings of known Heart Rate. Additional testing with the use of simulated recordings per ASTM EC13:2002.
- Actiheart Software Functional Requirements Test Procedure/Report; assesses the features of the Actiheart to ensure compliance with the Software requirements.
- Actiheart Shock & Vibration Test
- Actiheart Temperature & Humidity Test

Additional testing has been performed in to ensure safety & effectiveness of the Actiheart System. The following set of standards and guidance documents have been used in the design of the Actiheart System. These include:

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

- 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 {Biocompatibility has been established by the device clearances associated with the patient applied parts – no separate DOC is provided to demonstrate compliance with this standard}

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

- ANSI/ASTM EC13:2002 Cardiac monitors, heart rate meters, and alarms [applicable clauses]

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

- FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, May 2005
- 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

Assessment of non-clinical performance data

The performance of the *Actiheart* Recorder has been tested in accordance with applicable clauses of ANSI/AAMI EC13:2002, American National Standard for Heart Rate (HR) Meters. The categories of tests applied to the submitted Recorder are listed as follows:

- Tall T-wave rejection capability
- Measurement of HR sensitivity and specificity for several libraries of ECG waveforms
- Measurement of HR in the presence of line frequency and drift noise
- Measurement of range and accuracy of ECG detection
- Measurement of HR detection over a range of QRS amplitudes
- Accuracy and response to irregular rhythms

A detailed disclosure of the test results has been provided in Tab 5 of this Application. For all the categories, we have determined that *Actiheart* performance meets that of the currently-marketed predicate device, *Mini-Logger® Series 2000 Heart Rate Probe*. Neither the submitted device (*Actiheart*) nor the predicate device (*Mini-Logger® Series 2000 Heart Rate Probe*) is capable of detecting all types of irregular rhythms as specified in ANSI/AAMI EC13, Clause 4.1.2.1(e). However, per ANSI/AAMI EC13, a note has been placed in the *Actiheart* Instruction Manual indicating such. A summary of our results appears in Table 10D.

TABLE 10D. ACTIHEART HEART RATE MEASUREMENT CHARACTERISTICS

Figure of Merit	Requirement	Actiheart Performance
Tall T-wave Rejection Capability	Reject Tall T-Waves up to 1.2 mV with ±10% accuracy or ±5 BPM (greater of two)	Sensitivity is better than 98 % Specificity is 100%
MIT-BIH Normal Sinus Rhythm waveform library	Detect HR with accuracy of ±10% or ±5 BPM (greater of two)	Sensitivity is better than 99% Specificity is better than 98%
European ST-T waveform library	Detect HR with accuracy of ±10% or ±5 BPM (greater of two)	Sensitivity is better than 99% Specificity is better than 97%
AAMI Normal Sinus Rhythm waveform library	Detect HR with accuracy of ±10% or ±5 BPM (greater of two)	Sensitivity is better than 99% Specificity is better than 99%
Line frequency tolerance and drift tolerance	Detect HR with accuracy of ±10% or ±5 BPM (greater of two) when drift or line noise present	No difference between HR measurement for waveforms with and without superimposed noise
Range and accuracy of HR meter	Detect HR with accuracy of ±10% or ±5 BPM (greater of two) over specified range of 32 to 255 BPM	Within limits for all values of HR
Amplitude of QRS waveform	Detect HR with accuracy of ±10% or ±5 BPM (greater of two) for amplitudes 0.5 mV to 5 mV	Within limits for all values of amplitude between 0.45 mV and 9 mV.

Conclusion

It is the conclusion of Respironics that the Actiheart system is substantially equivalent to Mini Logger Series 2000 (K991045) and presents no new concerns about safety and effectiveness.

(End of Tab.)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 27 2005

Respironics, Inc.
c/o Mr. Neil E. Devine, Jr.
Responsible Third Party Official
Intertek Testing Services NA, Inc.
70 Codman Hill Road
Boxborough, Massachusetts 01719

Re: K052489
Trade/Device Name: Actiheart
Regulation Number: 21 CFR 882.1845
Regulation Name: Physiological signal conditioner
Regulatory Class: II
Product Code: GWK
Dated: September 8, 2005
Received: September 12, 2005

Dear Mr. Devine:

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), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K052489

Device Name: Actiheart

Indications for Use:

The *Actiheart* is an ambulatory Heart Rate and Activity Recorder. *Actiheart* may be used to quantifiably measure Heart Rate, Activity, and estimates of Caloric Expenditure. This device is not intended for use as an ECG monitor.

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)

Mark N. Milhorn

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

510(k) Number K052489