TAB 3

K061870

AUG 31 2006

510(K) SUMMARY OF SAFETY & EFFECTIVENESS

Official Contact

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Classification Reference 21 CFR 882.1845

Product Code GWK – Physiological Signal Conditioner

Common/Usual Name Physiological Signal Recorder

Proprietary Name Respironics VitalSense XHR

Predicate Device(s) VitalSense (K033534)
Actiheart (K052489)

Reason for submission Modified design.

Description of Device:

The subject device can be classified as physiological signal conditioner as described in 21 CFR 882.1845. VitalSense XHR is a physiological data recorder that is worn on the body. Up to ten sensor inputs may be used with a single VitalSense XHR recorder. The device senses and records physiological data and displays the data on its LCD screen. Recorded data may be transferred later to a PC for display and conversion for export to other programs.

Intended Use:

VitalSense XHR can be used in any setting where physiological body core temperature, skin temperature, or heart rate are used to further the understanding of body function or where quantifiable analysis of temperature or heart rate data is desirable.

Comparison of Technical Characteristics:

The VitalSense XHR System and the predicate devices are very similar in materials, design, function, and technological characteristics. The software in the predicate device, VitalSense (K033054), was modified to allow display of the heart rate data. No hardware modifications were required for the recorder. Results of performance tests, risk analysis, and verification and validation testing demonstrate that the devices are substantially equivalent. Accepted and voluntary standards are followed in the design, manufacture, and operation of this product.

Substantial Equivalence

The modified device has the following similarities to the previously cleared predicate device:

- ❑ Similar intended use.
- ❑ Same operating principle.
- ❑ Same technology.
- ❑ Same manufacturing process.

Design verification tests were performed on the Respironics VitalSense XHR as a result of the risk analysis and product requirements. All tests were verified to meet the required acceptance criteria. Respironics has determined that the modifications have no impact on the safety and effectiveness of the device. In summary, the device described in this submission is substantially equivalent to the predicate devices.

The modified device complies with the applicable standards referenced in the Guidance for FDA Reviewers and Industry "Guidance for the Content of Pre-market Submissions for Software Contained in Medical Devices," May 2006.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 31 2006

Ms. Zita A Yurko
Respironics, Inc.
Sleep & Home Respiratory Group
1001 Murry Ridge Lane
Murrysville, Pennsylvania 15668

Re: K061870
Trade/Device Name: VitalSense XHR
Regulation Number: 21 CFR 882.1845
Regulation Name: Physiological signal conditioner
Regulatory Class: Class II
Product Code: GWK
Dated: July 31, 2006
Received: August 1, 2006

Dear Ms. Yurko:

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) 276-0120. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

510(k) Number (if known): K061870

Device Name: Respironics VitalSense XHR

The VitalSense XHR can be used in any setting where physiological body core temperature, skin temperature, or heart rate are used to further the understanding of body function or where quantifiable analysis of temperature or heart rate data is desirable.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use XXXXX OR Over-The-Counter Use
(Per 21 CFR 801.109) (Optional Format 1-2-96)

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

510(k) Number K061870