SEP 2 2 2006

K060919

TAB 5

510(K) SUMMARY

RESPIRONICS INC.
1001 Murry Ridge Lane, Murrysville, PA 15668

510(k) Summary
ACTICAL

§807.92 (a)(1)

Contact Person: Zita Yurko
Manager, Regulatory Affairs

Date of Summary Preparation: October 14, 2005

§807.92 (a)(2)

Trade Name: Actical
Common Name: Physiological Signal Recorder
Classification Name: Physiological Signal Conditioner
Product Code: GWK

§807.92 (a)(3)

Legally Marketed Substantially Equivalent Device:

Actiwatch® (K983533)
Actiware-Sleep (K011430)
Actiheart (K052489)

§807.92 (a)(4)

Description of Device:

The subject device can be classified as physiological signal conditioner as described in 21 CFR 882.1845. *Actical* is a physiological data recorder consisting of a data recorder which can be worn on the waist (hip), wrist, or ankle of the subject and that detects, measures, and records physical Activity data. A *Reader* is used to transfer the recorded data to a Personal Computer (PC) running the Actical Host software. The host software is used to configure the data recorder for data collection, to retrieve logged

data from the recorder, to display data and trend graphs, and to provide a means to store the logged data in a PC for later use.

§807.92 (a)(5)

Intended Use:

The Actical is a compact, lightweight, waist-, wrist-, or ankle-worn activity monitor that may be used to assess human gross motor activity, caloric expenditure, and estimates of energy expenditure based on motor activity in any instance where quantifiable analysis of physical motion is desirable.

§807.92 (a)(6)

Comparison of Technical Characteristics:

The Actical System and the predicate devices are very similar in materials, design, function, and technological characteristics. Modifications to hardware and software subsystems of the predicate device system allow the subject device system, Actical, to record activity that is representative of energy expenditure. 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.

(End of Tab.)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Respironics, Inc.
% Intertek Testing Services
Mr. Neil Devine
2307 East Aurora Road
Twinsburg, Ohio 44087

SEP 2 2 2006

Re: K060919
Trade/Device Name: Actical
Regulation Number: 21 CFR 882.1845
Regulation Name: Physiological signal conditioner
Regulatory Class: Class II
Product Code: GWK
Dated: September 6, 2006
Received: September 7, 2006

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) 276-0120. 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,

Barbara Buehler for

Mark N. Melkerson
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): K060919

Device Name: Actical

Indications for Use:

The Actical is a compact, lightweight, waist-, wrist-, or ankle-worn activity monitor that may be used to assess human gross motor activity, caloric expenditure, and estimates of energy expenditure based on motor activity in any instance where quantifiable analysis of physical motion is desirable.

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)

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

510(k) Number K060919