K972829

RESPIRONICS®

OCT 28 1997

1001 Murry Ridge Drive
Murrysville, Pennsylvania
15668-8550 USA
Telephone: 1-412-733-0200
Fax: 1-412-733-0299

510(K) Summary - Cricket 2000 Pulse Oximeter 10/23/97

Reason for 510(k):
Modification to existing device, primarily replacing the DOS-based software with the Windows-based User Interface Software.

Device Description/ Intended Use/Indications for Use/Patient Population:
The Cricket 2000 is a recording pulse oximeter which measures functional blood oxygen saturation, pulse rate/interval and finger movement. Because of SpO2 and pulse rate alarm limits that can be set by the operator, it can be used for continuous monitoring. It also interfaces with a commercially available computer. The pulse oximetry, raw infrared and red waveform data, as well as the pulse rate data, can be viewed real-time on the computer using custom Windows®-based software that is provided with the pulse oximeter. The software also enables the user to do some data analysis, which can be used to draw meaningful implications during sleep apnea analysis studies. The Cricket 2000 is primarily indicated for use with patients suspected of suffering from, or with potential to suffer from, episodes of hypoxemia. The Cricket 2000 is intended for patients weighing more than 30 kg in both the hospital/institutional environment (supervised) and the home (unsupervised) environment.

Predicate Devices:
The predicate devices for the Cricket 2000 are the Vitalog VX4 Recording Pulse Oximeter (K935510) and the pulse oximetry component of the HMS series (K914620/A and K914085).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 28 1997

Mr. Francis X. Dobscha
Respironics, Inc.
1001 Murry Ridge Drive
Murrysville, Pennsylvania 15668-8550

Re: K972829
Cricket 2000 Pulse Oximeter
Regulatory Class: II (two)
Product Code: 74 DQA
Dated: July 29, 1997
Received: July 30, 1997

Dear Mr. Dobscha:

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): K 35510 modification

Device Name: Cricket 2000 (Pulse Oximeter)

Intended Use/Indications for Use

Intended Use/Indications for Use/Patient Population: The Cricket 2000 is a recording pulse oximeter which measures functional blood oxygen saturation, pulse rate/interval and finger movement. Because of SpO2 and pulse rate alarm limits that can be set by the operator, it can be used for continuous monitoring. It also interfaces with a commercially available computer. The pulse oximetry, raw infrared and red waveform data, as well as the pulse rate data, can be viewed real-time on the computer using custom Windows®-based software that is provided with the pulse oximeter. The software also enables the user to do some data analysis, which can be used to draw meaningful implications during sleep apnea analysis studies. The Cricket 2000 is primarily indicated for use with patients suspected of suffering from, or with potential to suffer from, episodes of hypoxemia. The Cricket 2000 is intended for patients weighing more than 30 kg in both the hospital/institutional environment (supervised) and the home (unsupervised) environment.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Christy Foreman for
(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices

510(k) Number K972829

Prescription Use ✓ OR Over-The-Counter Use
(Per 21 CFR 801.109)

(Optional Format 1-2-96)