K090273

510(k) SUMMARY JUN - 5 2009

Kai Sensors Non-Contact Respiratory Rate Spot Check Model 100

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

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Contact Person: Amy Droitcour

Date Prepared: May 8, 2009

Name of Device and Name/Address of Sponsor

Kai Sensors Non-Contact Respiratory Rate Spot Check Model 100 ("Kai RSpot 100") (K090273)

Common or Usual Name

Breathing Frequency Monitor (868.2375)

Classification Name

Class II, Product Code BZQ

Breathing Frequency Monitor (868.2375)

Predicate Devices

The Kai Sensors Non-Contact Respiratory Rate Spot Check Model 100 (K090273) is substantially equivalent to the Welch Allyn Propaq Encore Model 242 (K012451), the Welch Allyn Propaq CS (K012451), the Medcare Flaga Universal XactTrace (K043132), the Embla Embletta Gold (K073682), and the Ferguson Medical Somnologica software (as part of the Embla System, K971813).

Intended Use / Indications for Use

The Kai Sensors Non-Contact Respiratory Rate Spot Check Model 100 is intended for a one-time measurement of respiratory rate, as part of a vital signs assessment. The device is indicated for hospital or clinical use in adult patients. The device is intended to be operated by clinicians and medically qualified personnel. It is available for sale only upon the order of a physician or licensed health care provider.

The Kai Sensors Non-Contact Respiratory Rate Spot Check Model 100 is not intended to monitor vital signs. This device is not an apnea monitor

Technological Characteristics

The Kai Sensors Non-Contact Respiratory Rate Spot Check Model 100 ("Kai RSpot 100") is a reusable sensor for measuring respiratory rate during vital sign spot checks. The Kai RSpot 100 uses a low-power radar to sense chest displacement in order to obtain a respiratory rate. When the hardware module is operating and facing a patient, the Doppler radar transmits a low-power radio-frequency signal and receives the signal after it has reflected off the patient's torso. The receiver detects a phase shift on the signal due to chest displacement and converts this phase shift into a voltage that is digitized and sent to the computer portable computer via USB. The portable computer runs the Kai RSpot 100 software, which determines a respiratory rate from the chest motion (respiratory effort) signal and provides the display, user interface, and power source for the device. The portable computer can operate on battery power or on wall power through outlets when used with the supplied power cord.

Performance Data

The bench and clinical performance data demonstrates that the Kai RSpot 100 is as safe and effective as its predicate devices. The bench testing of this device demonstrates that the Kai RSpot 100 operates within its specifications, including accuracy over the range of measured respiratory rates. Clinical testing of the device demonstrated its ability to generate respiratory rate information of sufficient accuracy for its intended use.

Because the Kai RSpot 100 does not contact the patient, there is no risk of inadvertent exposure to electric current, and there are no patient-contacting materials that could cause allergic reactions or skin sensitivity. The radio signals emitted by the Kai RSpot100 are at a power well below that emitted by many consumer wireless devices and many medical devices.

Substantial Equivalence

The Kai RSpot100 and its predicate devices, which include the Welch Allyn Propaq 200-series monitors (K012451) and the Embletta Gold system with Universal XactTrace belts and Somnologica software (K043132, K073682, and K971813), have the same intended use and similar indications, technological characteristics and principles of operation.

The Kai RSpot 100, the Welch Allyn Propaq 200-series (K012451), and the Embla Embletta system with XactTrace belts and Somnologica software (K043132, K073682, and K971813) all provide a respiratory rate based on a respiratory effort measurement. The minor technological differences between the Kai RSpot 100 and its predicate devices raise no new issues of safety or effectiveness. The bench and clinical performance data demonstrate that the Kai RSpot 100 is as safe and effective as the Welch Allyn Propaq 200-series monitors (K012451) and the Embla Embletta Gold system with Medcare Flaga Universal XactTrace belts and Ferguson Medical Somnologica software (as part of Embla system) (K043132, K073682, and K971813). Thus, the Kai RSpot 100 is substantially equivalent to its predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Amy Droitcour
Technology Director
Kai Sensors, Incorporated
3465 Waialae Avenue, Suite 370
Honolulu, Hawaii 96816

JUN - 5 2009

Re: K090273
Trade/Device Name: Kai Sensors Non-Contact Respiratory Rate Spot Check Model 100 ("Kai RSpot 100")
Regulation Number: 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: II
Product Code: BZQ
Dated: May 8, 2009
Received: May11, 2009

Dear Ms. Droitcour:

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

Sincerely yours,

Susan Runner, D.D.S., M.A.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K090273

Device Name: Kai Sensors Non-Contact Respiratory Rate Spot Check Model 100 ("Kai RSpot 100")

Indications for Use:

The Kai Sensors Non-Contact Respiratory Rate Spot Check Model 100 is intended for a one-time measurement of respiratory rate as part of a vital signs assessment. The device is indicated for hospital or clinical use in adult patients. The device is intended to be operated by clinicians and medically qualified personnel. It is available for sale only upon the order of a physician or licensed health care provider.

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Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 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 Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K090273