K043604
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APR 2 9 2005

510(k) SUMMARY

VivoMetrics, Inc. LifeShirt™ Real-Time

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

VivoMetrics, Inc.
121 North Fir Street, Suite E
Ventura, California 93001
Phone: 805-667 -2225
Facsimile: 805-667 -6846
Contact Person: Keith Gilroy
Date Prepared: December 28, 2004

Name of Device and Name/Address of Sponsor

LifeShirt Real-Time

VivoMetrics, Inc.
121 North Fir Street, Suite E
Ventura, California 93001

Common or Usual Name

Programmable Diagnostic Computer

Classification Name

Programmable Diagnostic Computer

Predicate Devices

Reusable Multiple-Patient LifeShirt with VivoLogic Analysis Software

GMP Companies, Inc., LifeSync® Wireless ECG System

Life Sensing Instrument Company, Teletrens Model TM10 Multi-Parameter Portable Patient Transmitter

Mortara Instrument Inc., Ambulatory X-12 Telemetry Module

Purpose of the Special 510(k) notice.

The purpose of this Special 510(k) is to modify the LifeShirt. The only difference between the devices is that the new device is indicated for use with an optional temperature probe, which is supplied, and uses a wireless data card in its recorder to permit the wireless transmission of its recorded data to a networked computer.

Intended Use

The LifeShirt Real-Time is intended for use during daily activities of living and sleep, for the purpose of recording physiological data for later analysis by a physician. Respiration, ECG, pulse oximetry, blood pressure, temperature, and body position data may be collected. The system is intended to provide analysis of breathing patterns as an aid in classifying apneas as well as displaying heart rate changes from electrocardiographic waveforms in the wake and sleeping states as well as activities of daily living. The LifeShirt Real-Time is indicated for reuse by multiple adult patients in applications that may include pharmaceutical studies in which respiratory information is a useful indicator, or the general healthcare market where patients may be monitored at home and the data provided to their physicians as an aid to diagnosis and treatment.

Technological Characteristics

The LifeShirt Real-Time consists of the following components: the LifeShirt garment, LifeShirt Recorder/Transmitter, a wireless flash card, a data Flash Card, VivoMonitor™ real-time software and VivoLogic® analysis and reporting software. A cleared pulse oximeter, blood pressure cuff, and a temperature sensor are optional accessories provided for use with the device.

Performance Data

Performance testing included verification that data recorded by the LifeShirt recorder is accurately transmitted and received by the PC computer system. In addition, testing was performed to demonstrate electromagnetic compatibility.

Substantial Equivalence

LifeShirt Real-Time has the same intended use and similar indications, principles of operation, and technological characteristics as its predicate devices.

The minor differences in the LifeShirt Real-Time and the cleared LifeShirt which are the optional temperature probe and wireless communication do not raise any new questions of safety or effectiveness as the predicate devices have similar features. Performance data demonstrates that the LifeShirt Real-Time is as safe and effective as the predicate Multiple Patient Use LifeShirt. Thus, the LifeShirt Real-Time 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

APR 2 9 2005

Vivometrics, Inc.
c/o Mr Howard M. Holstein
Hogan & Hartson, L.L.P.
555 Thirteenth Street, NW
Washington, DC 20004-1109

Re: K043604
Trade Name: LifeShirt Rel-Time with Vivo Monitor Software
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II (two)
Product Code: DQK
Dated: April 15, 2005
Received: April 15, 2005

Dear Mr. Holstein:

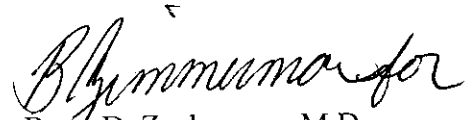
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K043604

Indications for Use Statement

510(k) Number (if known):_____

Device Name: LifeShirt Real-Time with Vivo Monitor Software

Indications for Use:

The LifeShirt Real-Time is intended for use during daily activities of living and sleep, for the purpose of recording physiological data for later analysis by a physician. Respiration, ECG, pulse oximetry, blood pressure, temperature, and body position data may be collected. The system is intended to provide analysis of breathing patterns as an aid in classifying apneas as well as displaying heart rate changes from electrocardiographic waveforms in the wake and sleeping states as well as activities of daily living. The LifeShirt Real-Time is indicated for reuse by multiple adult patients in applications that may include pharmaceutical studies in which respiratory information is a useful indicator, or the general healthcare market where patients may be monitored at home and the data provided to their physicians as an aid to diagnosis and treatment.

Prescription Use ✓ (Per 21 C.F.R. 801.109) AND/OR Over-The-Counter Use____ (Per 21 C.F.R. 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(K) Number K043604