K011903

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APR 12 2002

VivoMetrics

Makers of LifeShirt™

510(k) Summary

Submitter:	VivoMetrics, Inc.
Address:	121 North Fir Street, Suite E Ventura, CA 93001
Phone number:	(805) 667-2225
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Contact person:	Keith Gilroy
Date prepared:	June 15, 2001
Trade name:	LifeShirt System with VivoLogic Analysis Software
Common name:	Ambulatory Patient Monitor
Classification name:	Class II, Programmable Diagnostic Computer, 21 CFR 870.1425

Substantial equivalence claimed to:

1. RespiTrace PT, K942852, Non-Invasive Monitoring Systems, Inc.
2. RespiEvents 4.2, K001369, Non-Invasive Monitoring Systems, Inc.

Description:

The LifeShirt is a noninvasive ambulatory monitoring device that continuously monitors and stores respiration and ECG onto a CompactFlash™ memory card within a portable battery powered Handspring Visor® worn on a belt or within a pocket. The patient may be located at home or in an alternate care setting. The monitored subject can enter symptoms, activities, and medications into the Handspring Visor® that becomes part of the digital data stream. An optional NONIN pulse oximeter and Critikon noninvasive blood pressure monitor can be connected into the Visor for recordings during sleep or defined activities. The purpose of this system is to collect and store cardiac, respiratory, and blood pressure data as well as body position, various types of activities annotated with symptoms and a medication diary for subsequent analysis and archival at a data center utilizing the VivoLogic 1.0 software program. Data is transferred to the data center generally after the end of a patient data recording session.

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Intended use:

The LifeShirt System continuously records respiration, ECG, and body position signals for subsequent presentation and analysis by a licensed physician who reviews the data processed by VivoLogic on a personal computer. In addition, signals from external devices such as a pulse oximeter and blood pressure monitor can be collected and displayed. 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.

Summary of technological characteristics:

The LifeShirt system covered by this submission consists of four components, as described below.

1. LifeShirt data acquisition system: This includes the LifeShirt vest with Inductive Plethysmograph sensors, ECG sensors, a data cable, and the connected Handspring Visor® device with software for data collection and storage onto a Flash memory card. This technology is equivalent to that used in the currently marketed RespiTrace PT device.

2. LifeShirt Data Transfer software: This PC based software is used in transmitting the data from the user's PC to the VivoMetrics Data Center.

3. VivoMetrics Data Center: A database operated by VivoMetrics personnel which stores and provides an audit trail for data collected using the LifeShirt system.

4. VivoLogic 1.0 data analysis software: VivoLogic is a PC based application for viewing and analyzing patient data, used by Data Center personnel to provide information to health care providers. This software is equivalent to the currently marketed RespiEvents 4.2 software.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 4 2002

Keith Gilroy, Ph.D.
V.P. Product Development
VivoMetrics, Inc
121 North Fir Street, Suite E
Ventura, CA 93001

Re: K011903
Trade Name: LifeShirt System with VivoLogic Analysis Software
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II (two)
Product Code: DQK
Dated: February 14, 2002
Received: February 15, 2002

Dear Dr. Gilroy:

This letter corrects our substantially equivalent letter of April 12, 2002, regarding the indications for use statement.

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). 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); 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 continue 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 and additionally Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K011903

Device Name: LifeShirt System with VivoLogic Analysis Software

Indications for Use:

The Life Shirt system is intended for use by one adult 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, 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. Applications 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.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K011930

Prescription Use ✓
(Per 21 C.F.R. 801.109)

OR

Over-The-Counter Use____

(Optional Format 1-2-96)