K113045

510(k) Summary

(per 21 CFR 807.92)

AUG 14 2012

31 July 2012

Sponsor
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Consultant
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Proprietary Name:	BioHarness 3.0
Common Name	BioHarness 3.0
Device Classification Name	(1) Electrocardiograph Electrode (2) Arrhythmia Detector and Alarm
Classification Number:	(1) 21CFR870.2360 (2) 21CFR870.1025
Product Code	(1) DRX (2) MHX
Reviewing Group	Cardiovascular
Device Classification	Class II
Establishment registration No.	# 233836
Predicate Device	(1) Monebo, ***CardioBelt*** [tm], K063044, is a reusable electrode system consisting of an electrode assembly, an elastic chest, and an electronic package to transmit ECG information to a compatible Bluetooth enabled device. (2) Zephyr Technology, ***BioHarness 2.0***, K100040, is an ambulatory patient monitor consisting of a chest strap and an electronics module that attaches to the strap to acquire, store and transmit physiologic data.

Device Description

The BioHarness 3.0, a cardiographic electrode transmitter is composed of:

- proprietary hardware and firmware, enclosed in
- a user case (puck) with a re-chargeable battery,
- various sensors embedded in a reusable chest harness, and
- ECG detection and transmission and
- A cradle (to recharge battery and transfer internally stored date to an ancillary computer).

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The BioHarness 3.0 is a physiological / cardiographic electrode transmitter manufactured by Zephyr Technology Corporation with reusable electrodes in a chest harness consisting of an electrode assembly, an elastic chest belt, and an electronics package containing a Bluetooth transmitter. The BioHarness 3.0 electrodes are positioned against the patient's skin with light pressure, using the elastic chest belt. The BioHarness 3.0 is designed to be used without electrolytic gels and without adhesives on unprepared skin; that is without the requirements for shaving, abrading, or other skin preparation. This device transmits ECG information to a compatible Bluetooth - enabled device. This transmitter is a class I Bluetooth radio with a range of approximately 100 meters (spherical range).

Indications for Use

The BioHarness 3.0 is a physiological monitoring telemetry device intended for monitoring of adults in the home, workplace and alternate care settings. The device consists of a chest strap and an electronics module that attaches to the strap. The device stores and transmits vital sign data including ECG, heart rate, respiration rate, body orientation and activity. The BioHarness 3.0 provides a facility to detect and transmit single lead ECG signals to be received by Bluetooth / USB qualified ECG instruments.

The BioHarness 3.0 collects and transmits measurements captured during both sedentary as well as rigorous activity for Heart Rate, Posture and Activity. Breathing rate values are accurately transmitted only during sedentary periods.

The BioHarness 3.0 is indicated for use as a general patient monitor to provide physiological information as part of an occupational welfare monitoring system, for general research and performance measurement purposes, or where prescribed by a healthcare professional.

Intended Use

The **intended use** of the BioHarness 3.0 is to provide a facility in the home, workplace and alternate care settings for detecting, storing and transmitting Adult - single lead ECG data to third party ECG instruments for interpretation by qualified persons. The BioHarness 3.0 stores over 140 hours of ECG signals for transmission via USB or real time Bluetooth. The **scientific concept** on which this device is based is the principle that low level electrical pulses from the heart are measurable of the surface of the skin. This device **functions** by capturing these electrical pulses via electrodes and delivering these signals to sophisticated electronics for signal processing. The calibration is established by the factory and yields accurate and calibrated signals that can maintain calibration over its useful life.

Substantial Equivalence

Zephyr Technology Corporation has determined that the BioHarness 3.0 is substantially equivalent to the performance of a predicate Device. The differences between these systems are incidental and not significant. Both devices use a similar technological characteristics and principles.

- Both devices use electrodes to capture signals from the skin,
- both devices convert analog cardiological signals to digital signals,
- both devices use micro-processors, firmware and signal processing,
- both devices transmit the signals to receivers that detect and present the information as ECG waveforms.

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Safety and Effectiveness

There are no substantial differences between the BioHarness 3.0 defined in this 510(k) submission and the stated predicate device. They are similar to the technologies that are currently used in other similar medical devices.

This device is safe and effective for the application for which it is intended and has been tested to confirm safety and efficacy. A series of factory tests are conducted to verify the intended signals are accurate and can maintain a calibrated energy pattern over its useful life. The BioHarness 3.0 has benefited from design, development, testing and production procedures that conform to Quality Systems.

Zephyr Technology Corporation continues to search all appropriate sources for information relating to safety and effectiveness and maintains an *in-house* reporting device to identify adverse safety and effectiveness information and as such, applicable data is recorded for this product.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

AUG 14 2012

Zephyr Technology Corporation
c/o Mr. Richard Keen
Compliance Consultants
1151 Hope Street
Stamford, CT 06907

Re: K113045
Trade/Device Name: BioHarness 3.0
Regulation Number: 21 CFR 870.1025
Regulation Name: Monitor, Physiological, Patient (With Arrhythmia Detection or Alarms)
Regulatory Class: Class II (two)
Product Code: MHX, DRX
Dated: July 31, 2012
Received: August 9, 2012

Dear Mr. Keen:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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/CentersOffices/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/MedicalDevices/Safety/ReportaProblem/default.htm 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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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

Enclosure

K113045

510(K) Number Assigned k113045
Name: *BioHarness 3.0*

INDICATIONS FOR USE

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED) Concurrence of CDRH, Office of Device Evaluation (ODE)		
Prescription Use **___XXX___**	**or**	**Over - The - Counter Use** _____ **(Per 21 CFR 801.109)**
		(Optional Format 1-2-96

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Concurrence of CDRH, Office of ~~Device Evaluation (ODE)~~
(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K113045