Premarketing Notification

Traditional 510(k) Submission

DEC - 3 2010

Submission date:	December 31, 2009
Submitter	Zephyr Technology Corporation 1 Annapolis Street Suite 200 Annapolis, Maryland 21401
Contact Person:	Code Cubitt Chief Operating Officer Telephone: +1 (443) 569 3603 Fax: +1 (443) 926 9402
Common Name:	Ambulatory Patient Monitor
Trade Name:	BioHarness
Classification Name:	21CFR 870 1025
Establishment Registration Number:	
Product code:	MHX
Device Class:	Class II

1 GENERAL INFORMATION

This document contains the Premarket Notification for Zephyr Technology Corporation's BioHarness product. The BioHarness is an ambulatory patient monitor and provides remote vital signs monitoring for subjects in healthcare, occupational and home settings.

Zephyr's recommended classification for the BioHarness is as a class II medical device under regulation 21 CFR 870.1025 with product code MHX. The BioHarness product is a new medical device based on a legacy non-medical product already marketed by Zephyr. The intended use and technological characteristics of the BioHarness are the same as that of an existing legally marketed medical device manufactured by Hidalgo Ltd, the Equivital EQ-10 Vital Signs Physiological Monitor (K061993).

Zephyr Technology Corporation is a developer and manufacturer of real-time monitoring solutions for defense, emergency responder, training and research markets. Based in Annapolis, Maryland, Zephyr leverages a world class team of engineers, scientists, physiologists and business experts. Local universities and government labs augment Zephyr's internal development in specialized areas such as materials science, garment and textile design, sports science, physiological monitoring and software / web applications. Zephyr Technology Ltd, a wholly-owned R&D subsidiary of Zephyr Technology Corporation, is located in Auckland, New Zealand.

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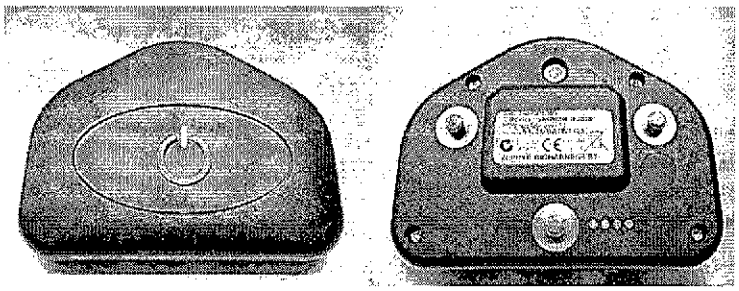
2 PROPOSED LABELLING

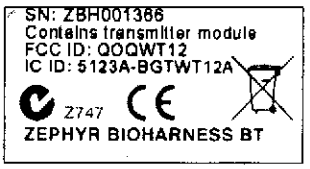
2.1 User Documentation

The user manual is available. "Zephyr Technology BioHarness Bluetooth User Manual"

Images of labels on the device are shown below.



Front and rear view of BioHarness device



Rear label

2.2 Carton Label

The BioHarness ships in a package 25.5cm x 16.5cm x 4.5cm. The figures below show the package labelling.

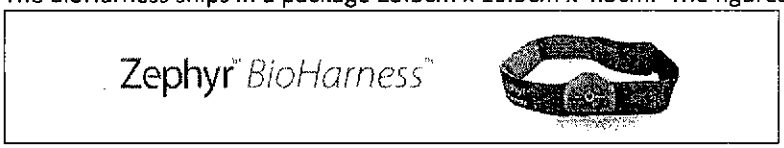


Figure 3.2.1 – BioHarness Carton Top

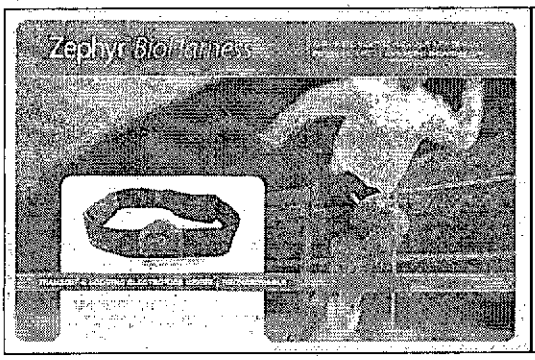


Figure 3.2.2 – BioHarness Carton Front

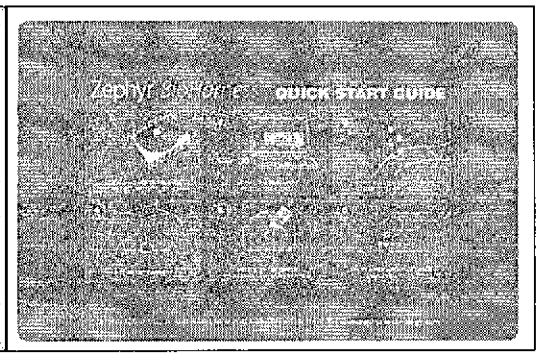


Figure 3.2.3 – BioHarness Carton Rear

Figure 3.2.4 – BioHarness Carton Bottom

3 SUBSTANTIAL EQUIVALENCE

The BioHarness and the Hidalgo Equivital EQ-10 Vital Signs Physiological Monitor are each ambulatory physiological monitoring devices capable of storing and transmitting multiple physiological parameters. Each of these devices is composed of two main components, a chest strap and a battery-powered electronics module. Both chest straps are used to sense heart electrical activity, thoracic movement and skin temp.

The physiological monitoring device presented in this 510(k) submission (BioHarness) is substantially equivalent to the physiological monitor marketed as the Hidalgo Equivital EQ-10 Vital Signs Physiological Monitor (K061993). Additional predicate devices include:

Respironics	Actiheart	K052489
VivoMetrics	LifeShirt Real Time	K043604
GMP|Wireless Medicine	LifeSync	K030795

A summary of similarities and differences between BioHarness and predicate devices are presented in the table below.

Table 5.1: Comparison To Predicate

Function	BioHarness	Predicate 1	Predicate 2
Heart Rate	A single-ended amplifier senses heart electrical activity through a chest strap with conductive fabric electrodes. The device filters and converts signal to digital form. The output is a digital value that corresponds to heart beats per minute.	Hidalgo Equivital EQ-10 K061993 Heart rate is derived from ECG sensed through a chest belt. A secondary measurement of R wave is also available.	Respironics Actiheart K052489 A differential amplifier senses and amplifies ECG through electrodes. The output is a digital value that corresponds to heart beats per minute.
Respiration Rate	Respiration rate is inferred from thoracic movement sensed by a chest strap containing a proprietary capacitive sensor. The thoracic movement waveform is amplified, digitized and analyzed to determine respiration rate.	Hidalgo Equivital EQ-10 K061993 Respiratory breathing frequency is inferred from thoracic cavity movement sensed by a chest belt containing an expansion sensor.	VivoMetrics LifeShirt Real Time K043604 Respiratory rate is derived from signals sensed via torso vest with embedded respiratory inductive plethysmography bands.
Skin Temperature	Measurement of skin temperature on the chest is performed with an integrated infrared thermometer.	Hidalgo Equivital EQ-10 K061993 Skin surface temperature.	
Activity/Body Orientation	The signal from an internal tri-axis accelerometer is digitized and analyzed using proprietary algorithms to determine activity and body orientation.	Hidalgo Equivital EQ-10 K061993 Activity and motion detection using a tri-axis accelerometer.	Respironics Actiheart K052489 The signal from an internal tri-axis accelerometer is used to detect motion.
Bluetooth Telemetry	An internal Bluetooth communications module is used to transmit digital physiological data.	Hidalgo Equivital EQ-10 K061993 Transmission of ECG data over Bluetooth.	GMP|Wireless Medicine LifeSync K030795 Transmission of ECG data over Bluetooth link.

4 510(K) EXECUTIVE SUMMARY

1.	Submitter:	Zephyr Technology Corporation 1 Annapolis Street Suite 200 Annapolis, Maryland 21401
2.	Contact Person:	Code Cubitt Chief Operating Officer Telephone: +1 (443) 569 3603 Fax: +1 (443) 926 9402
3.	Date submitted:	December 31, 2009
4.	Trade Name:	BioHarness
5.	Common Name:	Ambulatory Patient Monitor
6.	Classification Name:	21CFR 870 1025 Product code: MHX
7.	Predicate Device	Hidalgo Equivital EQ-10 (K061993) VivoMetrics LifeShirt Real Time (K043604) Respironics Actiheart (K052489) GMP|Wireless Medicine LifeSync K030795
8.	Substantial Equivalence Statement	The Zephyr Technology BioHarness is substantially equivalent in intended use to the Hidalgo Equivital EQ-10. The intended use and application of the proposed device are substantially equivalent to the legally marketed predicate device currently on the market.
9.	Device description	The BioHarness is a compact physiological monitor that consists of two components: 1. A chest strap with conductive fabric skin electrodes and a thoracic expansion sensor. 2. A battery-powered electronics module that attaches to the chest strap.

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The device provides both storage and real-time transmission of the user's Heart Rate and Respiration Rate. The device uses heart electrical activity signals and respiratory breathing frequency inferred from thoracic movement to derive the Heart Rate and Respiration Rate.

The device also provides the following physiological measures:

- An indication of the user's activity level based on acceleration measured by an internal triaxial accelerometer.
- Body orientation
- Thoracic skin temperature.
- Alerts if physiological conditions exceed predefined thresholds.

An accessory cradle is provided to recharge the internal battery and transfer internally stored data to a computer.

The transmitted data provided by the device over Bluetooth may be integrated into third party monitoring applications.

10. Intended use

The BioHarness 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 heart rate, respiration rate, thoracic skin temperature, body orientation and activity.

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

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

11. Technological characteristics

Substantial equivalence has been measured by review and comparison of performance data for the following. The technological characteristics compare to the following predicates:

Function	Predicate 1	Predicate 2
Heart Rate	Hidalgo Equivital EQ-10 K061993	Respironics Actiheart K052489
Respiration Rate	Hidalgo Equivital EQ-10 K061993	VivoMetrics LifeShirt Real Time K043604

Skin Temperature	Hidalgo Equivital EQ-10 K061993	
Activity/Body Orientation	Hidalgo Equivital EQ-10 K061993	Respironics Actiheart K052489
Bluetooth Telemetry	Hidalgo Equivital EQ-10 K061993	GMP|Wireless Medicine LifeSync K030795

12. Performance data

Performance measurement and review to the applicable sections of the following standards has been conducted and successfully demonstrated as recommended by available guidance from the agency:

ANSI/AAMI ES60601-1:2005, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.

ANSI/AAMI/IEC 60601-1-2:2007, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic Compatibility - Requirements and tests.

ANSI/AAMI/ISO 10993-1:2003, Biological evaluation of medical devices – Part 1: Evaluation and testing.

ANSI/AAMI EC13:2002/(R) 2007, Cardiac monitors, heart rate meters, and alarms. The device provides function as a heart rate meter, but is not indicated for use as an ECG monitor.

ASTM E1965 - 98(2009) Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature.

Reviews and tests have also been carried out for general functionality and performance of the BioHarness.

Software has been developed using a structured software development process which meets the requirements of IEC 60601-1-4:1996/(R)2005, Medical electrical equipment - Part 1: General requirements for safety. 4. Collateral Standard: Programmable electrical medical systems.

14. Conclusion

This pre-market notification has shown the substantial equivalence of the BioHarness to the identified predicates, by comparison to the descriptive material and performance testing of the device.

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5 DESCRIPTION OF DEVICE

The BioHarness is a compact physiological monitor that consists of two components:
1. A chest strap with conductive fabric skin electrodes and a thoracic expansion sensor.
2. A battery-powered electronics module that attaches to the chest strap.

The device provides both storage and real-time transmission of the user's Heart Rate, Respiration Rate, Temperature, Posture and Activity Level. The device uses heart electrical activity signals and respiratory breathing frequency inferred from thoracic movement to derive the Heart Rate and Respiration Rate respectively.

An accessory cradle is provided to recharge the internal battery and transfer internally stored data to a computer.

The transmitted data provided by the device over Bluetooth may be integrated into third party monitoring applications. A simple software utility that displays vital sign data is provided. Users may transmit vital sign data from the BioHarness to the application on a PC via Bluetooth using the Bluetooth adapter.

The figures below show the BioHarness and accessories.

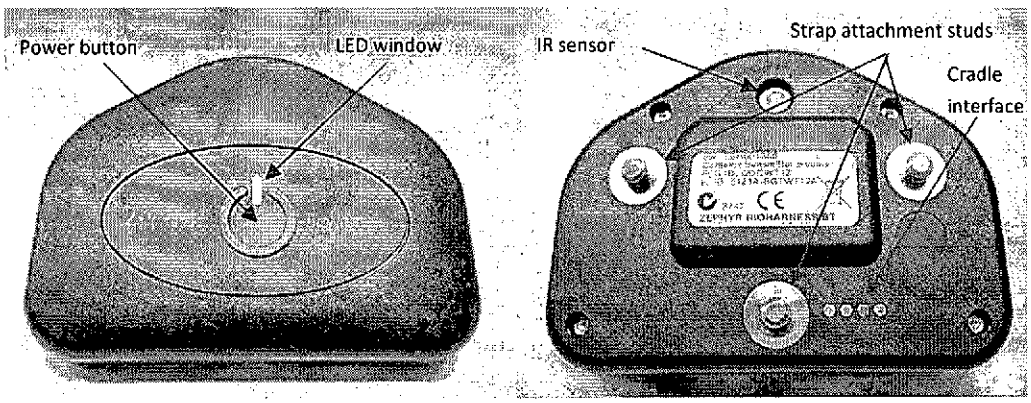

Figure 7.1 – BioHarness, external front and rear views

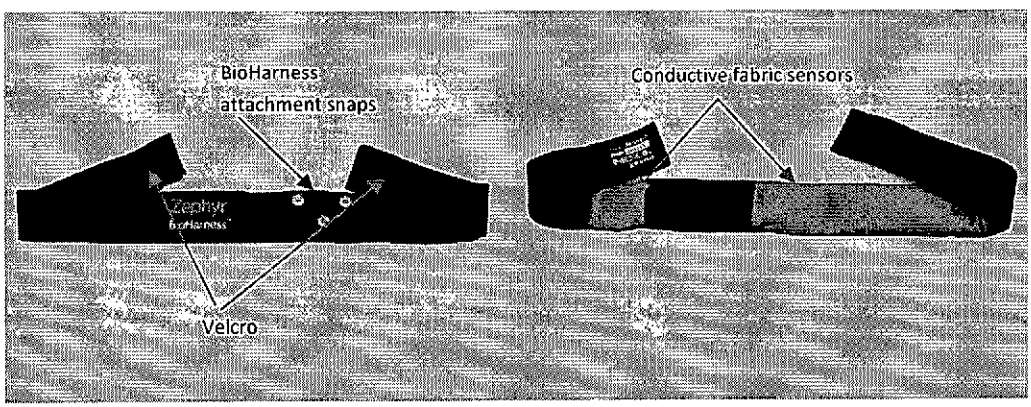

Figure 7.2 – BioHarness strap, front and rear views

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6 TECHNOLOGICAL CHARACTERISTICS

The technological characteristics of the BioHarness are described in the following sections.

6.1 General Functionality

The BioHarness stores and transmits physiological data including heart rate, respiration rate, thoracic skin temperature, body orientation and activity level. The digital data are derived from physiological signals acquired from the user through the chest strap for heart rate and respiration rate. An infrared sensor is used to measure skin temperature on the user's chest. The user's activity and body orientation are derived from accelerometry signals from an internal triaxial accelerometer. Data may be transmitted over Bluetooth to a computer. The BioHarness has an internal rechargeable lithium polymer battery.

A. Heart Rate

The BioHarness monitors electrical signals produced by the heart through a chest strap with conductive fabric skin electrodes and derives heart rate based on proprietary analysis of the QRS complex. The BioHarness is not an ECG monitor and provides no analysis capability in cases of abnormal QRS complex. The chest strap uses conductive lycra fabric to form a sensor, measuring electrical activity in the V4 lead position (fifth intercostals space in the midclavicular). A single-ended ECG circuit is used to detect QRS complexes. The circuit incorporates ESD protection, both passive and active filtering and an ADC to convert the signal to a digital representation. Proprietary digital filtering and signal analysis is performed on the signal with a microcontroller circuit to derive heart rate.

B. Respiration Rate

The BioHarness monitors thoracic movement (chest expansion and contraction) through a chest strap containing a proprietary capacitive sensor. The capacitive sensor is composed of layers of conductive fabric, foam and flexible mylar (dielectric). The sensor capacitance is driven with a low-level 500kHz PWM signal. Thoracic expansion and contraction cause changes in capacitance which in turn result in changes in impedance causing the amplitude of the drive signal to vary. The BioHarness respiration circuit detects, filters and amplifies this change in amplitude to produce a varying voltage signal that represents thoracic movement. The signal is passed to an ADC and proprietary digital filtering and signal analysis is performed with a microcontroller circuit to derive respiration rate. Respiration rate is inferred by thoracic movement measured via the capacitive sensor and circuit.

C. Skin Temperature

The BioHarness uses an infrared thermometer to perform non-contact temperature measurements on user's chests. The infrared thermometer is mounted internal to the device, but has a viewing window that faces the user's chest. The Hidalgo uses a thermistor in the sensor module near an ECG electrode to measure skin temperature. Both sensors provide similar accuracy in temperature measurement.

D. Body Orientation

The BioHarness measures body orientation by proprietary analysis of acceleration values output by an internal precision triaxial accelerometer and provides a measure of user posture (upright, supine, prone) in degrees from vertical. The Hidalgo device calculates body orientation using three orthogonal accelerometer channels.

E. Activity

The BioHarness measures activity level by proprietary analysis of acceleration values output by an internal precision triaxial accelerometer (Analog Devices ADXL330 3-axis +/-3 g iMEMS) and provides activity level in Vector Magnitude Units (VMU). The Hidalgo device calculates activity using three orthogonal accelerometer channels.

6.2 Basic Safety and Essential Performance

The BioHarness meets the relevant requirements of ANSI/AAMI ES60601-1:2005, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.

1. Electrical Safety

A review of ANSI/AAMI ES60601-1:2005 has been conducted with respect to electrical hazards, with specific attention given to the relevant subclauses in clauses 8, 13 and 4. The risks associated with electrical hazards were assessed in accordance with Zephyr's risk management procedure. The subclauses relevant for Zephyr's device are discussed below.

2. Mechanical Safety

A review of ANSI/AAMI ES60601-1:2005 has been conducted with respect to mechanical hazards, with specific attention given to the relevant subclauses in clauses 9, 13 and 4. The risks associated with mechanical hazards were assessed in accordance with Zephyr's risk management procedure. The subclauses relevant for Zephyr's device are discussed below.

3. Radiation Hazards

A review of ANSI/AAMI ES60601-1:2005 has been conducted with respect to radiation hazards, with specific attention given to the relevant subclauses in clauses 10, 13 and 4. The risks associated with these hazards were assessed in accordance with Zephyr's risk management procedure. The subclauses relevant for Zephyr's device are discussed below.

4. Temperature and Other Safety Concerns

A review of ANSI/AAMI ES60601-1:2005 has been conducted with respect to excessive temperatures and other hazards, with specific attention given to the relevant subclauses in clauses 11, 13 and 4. The risks associated with these hazards were assessed in accordance with Zephyr's risk management procedure.

5. Accuracy of Controls and Protection Against Hazardous Outputs

A review of ANSI/AAMI ES60601-1:2005 has been conducted with respect to accuracy of controls and instruments and protection against hazardous outputs, with specific attention given to the relevant subclauses in clauses 12, 13 and 4. The risks associated with these hazards were assessed in accordance with Zephyr's risk management procedure

6. Hazardous Situations and Fault Conditions

A review of ANSI/AAMI ES60601-1:2005 has been conducted with respect to hazardous situations and fault conditions, with specific attention given to the relevant subclauses in clauses 13 and 4. The risks associated with these hazards were assessed in accordance with Zephyr's risk management procedure.

7. Construction of ME Equipment

A review of ANSI/AAMI ES60601-1:2005 has been conducted with respect to construction of ME Equipment, with specific attention given to the relevant subclauses in clauses 15, 13 and 4. The risks associated with these hazards were assessed in accordance with Zephyr's risk management procedure.

8. Electromagnetic Compatibility

The BioHarness has been tested and shown to be compliant with electromagnetic compatibility requirements in the US (FCC) and the EU (R&TTE Directive).

The BioHarness complies with FCC Part 15 Subparts A and B as a Class B Unintentional Radiator (using methods described in ANSI C63.4 – 2003). The BioHarness also complies with the essential requirements of the R&TTE Directive. The BioHarness complies with EN 301 489-17 V1.2.1 (2002-08) when tested in accordance with EN 301-489-1 V1.6.1 (2005-09).

The AC Adapter complies with the requirements of the electrical safety standard AS/NZS 60950.1:2003 + A1 + A2 + A3.

9. Biocompatibility

The BioHarness meets the relevant requirements of ANSI/AAMI/ISO 10993-1:2003, Biological evaluation of medical devices – Part 1: Evaluation and testing.

10. Cardiac monitoring

The BioHarness meets the relevant requirement for heart rate metering in ANSI/AAMI EC13:2002/(R) 2007, Cardiac monitors, heart rate meters, and alarms.

11. Infrared Thermometry

The BioHarness meets the relevant requirements of ASTM E1965 - 98(2009), Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature.

12. Software

The BioHarness software has been developed using a structured software lifecycle which meets the requirements of IEC 60601-1-4:1996/(R)2005, Medical electrical equipment - Part 1: General requirements for safety. 4. Collateral Standard: Programmable electrical medical systems.

7 PERFORMANCE DATA

Reviews and tests have been carried out for general functionality and performance of the BioHarness.

Additional performance measurement and review to the applicable sections of the following standards has been undertaken and successfully demonstrated as recommended by available guidance from the agency:

ANSI/AAMI ES60601-1:2005, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

ANSI/AAMI/IEC 60601-1-2:2007, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic Compatibility - Requirements and tests

ANSI/AAMI/ISO 10993-1:2003, Biological evaluation of medical devices – Part 1: Evaluation and testing

ANSI/AAMI EC13:2002/(R) 2007, Cardiac monitors, heart rate meters, and alarms

ASTM E1965 - 98(2009) Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature

The BioHarness software has been developed using a structured software lifecycle which meets the requirements of IEC 60601-1-4:1996/(R)2005, Medical electrical equipment - Part 1: General requirements for safety. 4. Collateral Standard: Programmable electrical medical systems

7.1 General Functionality

General functionality of the BioHarness has been reviewed and tested iteratively throughout the development cycle. Devices and accessories are also tested as part of the production process.

Development testing of BioHarness functionality has occurred at the bench level and under simulated field conditions (i.e. field trials).

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

Zephyr Technology Corporation
c/o Mr. Code Cubitt
Chief Operating Officer
1 Annapolis Street, Suite 200
Annapolis, MD 21401

DEC - 3 2010

Re: K100040
Trade/Device Name: BioHarness
Regulation Numbe r: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector and Alarm (Including ST-Segment Measurement and Alarm)
Regulatory Class: Class II (two)
Product Code: MHX
Dated: Undated
Received: December 1, 2010

Dear Mr. Cubitt:

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/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,

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

Enclosure

DEC - 3 2010

ZEPHYR TECHNOLOGY BIOHARNESS

INDICATIONS FOR USE STATEMENT

510(k)Number (If Known): K100040

Device Name: BioHarness

Indications for Use:

The BioHarness 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 heart rate, respiration rate, thoracic skin temperature, body orientation and activity.

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

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

Prescription Use <√> AND/OR Over-The-Counter-Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence by CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K100040