DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

August 23, 2017

NimbleHeart, Inc.
Sonal Tambe
Chief Executive Officer
1300 White Oaks Rd., Suite #201
Campbell, California 95008

Re: K171244
Trade/Device Name: Physiotrace™ Smart
Regulation Number: 21 CFR 870.2360
Regulation Name: Electrocardiograph Electrode
Regulatory Class: Class II
Product Code: DRX, MWI, MHX
Dated: July 15, 2017
Received: July 17, 2017

Dear Sonal Tambe:

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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,

Jessica E. Paulsen -S

for

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K171244

Device Name

Physiotrace[tm] Smart

Indications for Use *(Describe)*

The Physiotrace[tm] Smart is a telemetry device intended for physiological monitoring of men and women above 18 years of age at home, workplace, exercise facilities and alternate care settings. The Physiotrace[tm] Smart records single lead ECG data for up to 60 minutes during resting and exercise activities; and transmits it to a server for review by healthcare team. The Physiotrace[tm] Smart 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.

The Physiotrace[tm] Smart is not indicated for use on critical care patients. The Physiotrace[tm] Smart is not indicated for diagnosis of cardiac conditions.

Contra-Indications

The Physiotrace[tm] Smart is contra-indicated for surgical procedures.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

Preparation Date

August 17, 2017

Company Information

Sonal Tambe
NimbleHeart, Inc.
1300 White Oaks Rd., #201
Campbell CA 95008 USA
408 475 7630
regulatory@nimbleheart.com

Identification of Product and Classification

Proprietary Name:	Physiotrace Smart
Common Name:	ECG Monitor
Classification Name:	Monitor,Physiological,Patient(Without Arrhythmia Detection Or Alarms)
Regulation Description:	Cardiac monitor (including cardiotachometer and rate alarm).
Classification Panel:	Cardiovascular
Device Class:	II
Product Code:	DRX, MWI
CFR Section:	870.2360, 870.2300
Predicate Device:	BioHarness 3.0 by Zephyr Technology Corporation K113045

Device Description

The Physiotrace[tm] Smart has a wearable and reusable design that can be wrapped and fastened around the torso. The device uses dry ECG electrodes and embeds an ECG acquisition unit with a Bluetooth Low Energy transmitter. A mobile application controls the data acquisition, displays the status of the device, heart rate and optionally the ECG waveform during a recording session. The mobile App also stores the ECG and the exercise session information and relays it to a cloud server for permanent storage and review by healthcare staff. The Physiotrace[tm] Smart is designed to be used without electrolytic gels and without adhesives that necessitate skin preparation.

Indications of Use

The Physiotrace[tm] Smart is a telemetry device intended for physiological monitoring of men and women above 18 years of age at home, workplace, exercise facilities and alternate care settings. The Physiotrace[tm] Smart records single lead ECG data for up to 60 minutes during resting and exercise activities; and transmits it to a server for review by healthcare team. The Physiotrace[tm] Smart 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.

The Physiotrace[tm] Smart is not indicated for use on critical care patients. The Physiotrace[tm] Smart is not indicated for diagnosis of cardiac conditions.

Contra-Indications

The Physiotrace[tm] Smart is contra-indicated for surgical procedures.

510(k) Summary

Indications of use comparison		
Parameter	**Physiotrace Device**	**Predicate Device**
FDA 510(k) Number	K171244	K113045
Applicant	NimbleHeart, Inc.	Zephyr Technology Corp.
Device Name	Physiotrace Smart	BioHarness 3.0
Classification Regulation	870.2360, 870.2300	870.2360, 870.1025
Product Code	DRX, MWI	DRX, MHX
Intended population and locations	The Physiotrace Smart is a telemetry device intended for physiological monitoring of men and women above 18 years of age at home, workplace, exercise facilities and alternate care settings.	The BioHarness 3.0 is a physiological monitoring telemetry device intended for monitoring of adults in the home workplace and alternate care settings.
Indicated use scenario	The Physiotrace Smart records single lead ECG data for up to 60 minutes during resting and exercise activities; and transmits it to a server for review by healthcare team.	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.
Indications for use	The Physiotrace^{tm} Smart 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. Physiotrace Smart is not indicated for use on critical care patients. The Physiotrace^{tm} Smart is not indicated for diagnosis of cardiac conditions.	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.
Product Design	The device has a wearable and reusable design that can be wrapped and fastened around the torso. The device uses dry ECG electrodes and embeds an ECG acquisition unit with a Bluetooth Low Energy transmitter. A mobile application controls the data acquisition, displays the status of the device, heart rate and optionally the ECG waveform during a recording session. The mobile App also stores the ECG and the exercise session information and relays it to a cloud server for permanent storage and review by healthcare staff.	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.

510(k) Summary

Technological characteristics comparison		
Parameter	**NimbleHeart Physiotrace**	**Predicate Device**
ECG Electrodes	Gold plated brass electrodes	Silver fabric electrodes
Lead off detection	Lead off detection feature for Right and Left electrodes	Single indication called of Strap on/ off
Performance comparison		
ECG Performance standards met	60601-2-47	EC38
Bluetooth radio version	BT 4.0 (Max Tx power 4 dBm)	BT 2.1 + EDR (Max Tx power 10 dBm)

Safety and Effectiveness

The Physiotrace testing has confirmed this device meets it's the performance requirements of recognized standards for Medical device safety, biocompatibility, Electromagnetic Compatibility and for home use. A clinical study was performed during the exercise scenario as per the intended use. The device performance and safety and effectiveness was found to be equivalent or better than the predicate device.

Substantial Equivalence

The NimbleHeart Inc., Physiotrace Smart is a Class II device that is substantially equivalent to the designated predicate device.

The indications of use scenario where Physiotrace is slightly different is that the recording session time is pre-programmed with a default of 60 minutes for a prescribed exercise session. The mobile App logs out and stops data recording when the session ends. This feature reduces the risk posed by off label use of the device in critical care scenarios. The 60 minutes recording session was shown to be safe and effective during the clinical study.

The technological differences are mainly the electrode design including the materials used. The electrode performance has been tested as per the FDA's electrode guidance document. It was also validated during a clinical study and found comparable to that of the predicate device. All the materials have passed biocompatibility and cleaning validation tests.

Therefore, Physiotrace Smart is as safe and effective as the predicate device and can therefore be found to be substantially equivalent.