December 15, 2017

Biotricity Inc.
% Mark Job
Official Correspondent
Regulatory Technology Services, LLC
1394 25th Street, NW
Buffalo, Minnesota 55313

Re: K172311
Trade/Device Name: BioFlux Device
Regulation Number: 21 CFR 870.2920
Regulation Name: Telephone Electrocardiograph Transmitter and Receiver
Regulatory Class: Class II
Product Code: DXH
Dated: November 14, 2017
Received: November 21, 2017

Dear Mark Job:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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)*

K172311

Device Name

BioFlux Device

Indications for Use *(Describe)*

The **bio**flux Device is intended for use by patients who either have or are at risk of having cardiac disease and those that demonstrate intermittent symptoms indicative of cardiac disease and require cardiac monitoring on a continuing basis for up to 30 days. The device continuously records ECG data and upon detection by an ECG analysis algorithm or manually initiated by the patient, automatically delivers the recorded cardiac activity to the server where it is presented and can be reviewed by a medical professional.

The data received from the **bio**flux device can be used by another device for arrhythmia analysis, reporting and signal measurements. The **bio**flux device is not intended to sound any alarms. The device does not deliver any therapy, administer any drugs, provide interpretive or diagnostic statements or provide for any life support.

bioflux is for prescription use only.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

(as required by 21CFR 807.92)

I. SUBMITTER

Biotricity – Measuring Vitals
275 Shoreline Drive, Suite 150
Redwood City CA 94065
Contact Person: Spencer LaDow
sladow@biotricity.com
Phone: 585-414-7407
Date Prepared: November 14, 2017

II. DEVICE

Name of Device: BioFlux Device
Classification Name: 870.2920
Telephone electrocardiograph transmitter and receiver.
Common or Usual Name: Mobile Cardiac Monitor
Device Panel: Cardiovascular
Regulatory Class: Class 2
Product Code: DXH

III. PREDICATE DEVICE

The **bio**flux System is substantially equivalent in intended use and similar technological characteristics the following device, Rhythmedix, LLC. RhythmStar System which was cleared under K141813.

IV. DEVICE DESCRIPTION

The **bio**flux system consists of the **bio**flux device and the server. The **bio**flux device is a portable, battery-powered, wireless cardiac monitor which may be worn by a patient to record ECG and activity level data for up to 30 consecutive days. The device can capture patient activated and auto-triggered events such as Bradycardia, Tachycardia, pause and Atrial Fibrillation as identified by an embedded arrhythmia detection algorithm. The device is designed to automatically deliver the data to the server. The data is delivered to the server wirelessly via mobile cellular dedicated network connection. A medical professional, using the server, can adjust and program the device configuration and auto-triggering parameters.

bioflux device is not a life-supporting or life-sustaining system. Clinical judgment and experience are used to check and interpret the data.

V. INDICATIONS FOR USE

The **bio**flux Device is intended for use by patients who either have or are at risk of having cardiac disease and those that demonstrate intermittent symptoms indicative of cardiac disease and require cardiac monitoring on a continuing basis for up to 30 days. The device continuously records ECG data and upon detection by an ECG analysis algorithm or manually initiated by the patient, automatically delivers the recorded cardiac activity to the server where it is presented and can be reviewed by a medical professional.

The data received from the **bio**flux device can be used by another device for arrhythmia analysis, reporting and signal measurements. The Bioflux device is not intended to sound any alarms. The device does not deliver any therapy, administer any drugs, provide interpretive or diagnostic statements or provide for any life support. **bio**flux is for prescription use only.

VI. SUMMARY OF TECHNOLIGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The **bio**flux system is substantially equivalent in intended use and similar technological characteristics of RhythmStar System cleared under K141813.

Category	**Identical/ Different**	**bio**flux	**RhythmStar**
510(k) Number		K172311	K141813
Classification Name	Identical	Medical Mobile Cardiac Monitor	Medical Mobile Cardiac Monitor
Product Code	Similar	DXH	DXH
Intended Use	Similar	The **bio**flux Device is intended for use by patients who either have or are at risk of having cardiac disease and those that demonstrate intermittent symptoms indicative of cardiac disease and require cardiac monitoring on a continuing basis for up to 30 days. The device continuously records ECG data and upon detection by an ECG analysis algorithm or manually initiated by the patient, automatically delivers the recorded cardiac activity to the server where it is presented and can be reviewed by a medical professional. The data received from the **bio**flux device can be used by another device for arrhythmia analysis, reporting and signal measurements. The **bio**flux device is not intended to sound any alarms. The device does not deliver any therapy, administer any drugs, provide interpretive or diagnostic statements or provide for any life support. Bioflux is for prescription use only.	The RhythmStar system is intended for use by patients who either have or are at risk of having cardiac disease and those that demonstrate intermittent symptoms indicative of cardiac disease and require cardiac monitoring on a continuing basis. The device continuously records ECG data and upon detection by an ECG analysis algorithm or manually initiated by the patient, automatically delivers the recorded cardiac activity to the server where it is presented and can be reviewed by a medical professional. The data received from the RhythmStar device can be used by another device for arrhythmia analysis, reporting and signal measurements. The RhythmStar system is not intended to sound any alarms. The device does not deliver any therapy, administer any drugs, provide interpretive or diagnostic statements or provide for any life support. RhythmStar is for prescription use only.
Delivered device includes	Similar	**bio**flux device -patient 3 lead ECG cable	RhythmStar monitor - Patient 3 lead ECG lead cable

Category	Identical/ Different	**bio**flux	RhythmStar
		-internal rechargeable battery -Wall Battery charger -Carry pouch	-- 2 externally re-chargeable batteries - Wall battery charger
Monitor functional blocks	Similar	analog ECG front end, MCU, flash data storage, RF modem for data transmission, LCD screen, and Record button	analog ECG front end, accelerometer, MCU, flash data storage, RF modem for data transmission, LCD screen, and Record button
The server:	identical	facilitate data communication with the **bio**flux device, provide data storage, and present the data for evaluation by a medical professional	facilitate data communication with the RhythmStar device, provide data storage, and present the data for evaluation by a medical professional
Device form factor	Similar	small, lightweight ambulatory cardiac monitors.	small, lightweight ambulatory cardiac monitors.
Wireless technology used to transmit data to server	Identical	Yes	Yes
Device is battery powered by a rechargeable Li-Ion battery	Identical	Yes	Yes
using a server, can adjust device programming parameters such as pre-post recording times and auto-triggering configuration.	Identical	Yes	Yes

Category	Identical/ Different	**bio**flux	RhythmStar
Devices incorporate an accelerometer to capture activity level data related to patient motion and device orientation.	Different	No	Yes
devices have Record button for manual event recordings and a user interface to indicate device status and mode of operation.	similar	Yes	Yes
Device incorporate embedded ECG analysis algorithm to auto-capture Bradycardia, Tachycardia and Atrial Fibrillation and arrhythmia events between the signal acquisition point and the server.	Similar	Yes	Yes
device has at least 2 ECG channels and 3-lead electrodes	Similar	Yes	Yes
Functional, Environmental and Electrical characteristics	Similar	Yes	Yes
USB connection	different	Yes, used to charge the battery, marks ECG data during recording in case noise is introduced, not used for data download.	Yes, used only for data download and secondary communication, cannot be connected during ECG recording

VII. PERFORMANCE TESTING

The following performance and safety tests have been passed successfully:

- IEC 60601-2-47:2012 Medical electrical equipment - Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems.
- IEC 60601-1:2012 3rd Edition with amendment 1, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
- IEC 60601-1-2:2014 4th Edition, Medical Electrical Equipment – Part 1-2: General requirements for basic safety and essential performance– Collateral standard: Electromagnetic compatibility – Requirements and tests.
- IEC 60601-1-11:2015 Edition 1.1, Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.
- ANSI/AAMI-EC 57:2012, Testing and Reporting Performance Results of Cardiac Rhythm and ST Segment Measurement Algorithms.
- IEC 62366-1:2015 Edition 1.0, Medical devices – Part 1: Application of usability engineering to medical devices
- Biocompatibility testing of patient contacting materials according to ISO 10993-1.
- Bench test results verify that Bioflux Monitor system can continuously record ECG signal, store ECG data in the device memory, and transmit manual or auto activated event recordings to the server via mobile network connection for evaluation by a medical professional. Test results verify that all requirements were met and that the Bioflux Monitor performs as designed.

VIII. SUBSTANTIAL EQUIVALENCE RATIONALE

The intended use, performance and technological characteristics of the **bio**flux Monitor system compared to the named predicate device demonstrates that the **bio**flux Monitor is substantially equivalent to the predicate.

IX. CONCLUSIONS

The analysis of the differences between **bio**flux Monitor and the predicate deice does not raise new questions of safety and effectiveness. Based on device performance test results, Biotricity determines that the **bio**flux Monitor system performs within its design specifications, and is substantially equivalent to the predicate devices.

The information in this 510(k) submission demonstrates that the **bio**flux Monitor system is substantially equivalent to the predicate device.