



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

October 13, 2016

Biotricity Inc.
% Mr. Mark Job
Third Party Reviewer
Regulatory Technology Services LLC
1394 25th Street, NW
Buffalo, Minnesota 55313

Re: K162571
Trade/Device Name: Bioflux Software
Regulation Number: 21 CFR 870.2800
Regulation Name: Medical Magnetic Tape Recorder
Regulatory Class: Class II
Product Code: DSH
Dated: September 14, 2016
Received: September 15, 2016

Dear Mr. 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.

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 yours,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman", is written over a large, semi-transparent blue watermark of the letters "FDA". The word "for" is written in small black text below the signature.

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

Enclosure

Indications for Use

510(k) Number (if known)

K162571

Device Name

Bioflux software

Indications for Use (Describe)

Bioflux software is intended to be used to analyze, view, and report ECG data acquired from a variety of ECG sources including single and 3-lead ECG devices. Bioflux software is operated locally in a browser and data is accessed via the users' credentials on the hardware platform running the browser.

It will be used by cardiologists, general practitioners, cardiac, or ECG technicians, nurses, monitoring service technicians, and other cardiac related institutions, or care givers, in independent clinical testing facilities, clinics, hospitals, physician's offices, or anywhere a physician or qualified non-physician practitioners deems appropriate

Bioflux software does not offer diagnosis, or medical alarms. It is intended that competent human intervention be involved before any impact on health occurs. Clinical judgement and experience are used to check and interpret the data.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASTaff@fda.hhs.gov

"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 Inc.
75 International Blvd, Suite 300
Toronto ON M9W 6L9
Canada
Contact Person: Tom Elias
telias@biotricity.com
Phone: 416.931.9001
Date Prepared: October 13, 2016

II. DEVICE

Name of Device: Bioflux Software
Classification Name: Recorder, Magnetic Tape, Medical
Common or Usual Name: Medical Magnetic Tape
Recorder
Device Panel: Cardiovascular
Regulatory Class: Class II
Product Code: DSH

III. PREDICATE DEVICE

The Bioflux Software is substantially equivalent in intended use and similar technological characteristics the following device, CardioComm Solutions, Inc. Guava II which was cleared under K122632.

IV. **DEVICE DESCRIPTION**

Bioflux software is an API based ECG viewer software that can display ECG records and provide tools for trained clinicians to analyze those ECG recordings. It is utilized by manually opening up ECG files of supported formats into the viewer.

Bioflux software fulfills all of the following:

- It is a cardiology software product, delivered on disk using the Single Page Application model.
- It operates on 2015 or later versions of Chrome and Firefox browsers.
- The data can be opened manually or entered via keyboard, mouse or touchscreen whereupon it gets sent to the browser for viewing analysis and storage.
- Information can be displayed on the display or printed via the browser.

Bioflux software 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**

Bioflux software is intended to be used to analyze, view, and report ECG data acquired from a variety of ECG sources including single and 3-lead ECG devices. Bioflux software is operated locally in a browser and data is accessed via the users' credentials on the hardware platform running the browser.

It will be used by cardiologists, general practitioners, cardiac, or ECG technicians, nurses, monitoring service technicians, and other cardiac related institutions, or care givers, in independent clinical testing facilities, clinics, hospitals, physician's offices, or anywhere a physician or qualified non-physician practitioners deems appropriate

Bioflux software does not offer diagnosis, or medical alarms. It is intended that competent human intervention be involved before any impact on health occurs. Clinical judgement and experience are used to check and interpret the data.

VI. SUMMARY OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Bioflux software is substantially equivalent in intended use and similar technological characteristics of Guava II cleared under K122632.

Category	Identical/ Different	Bioflux	Guava II
510(k) Number		K162571	K122632
Classification	Identical	Medical	Medical
Name		Magnetic Tape Recorder	Magnetic Tape Recorder
Product Code	Similar	DSH	DSH, DPS
Intended Use	Similar	<p>Bioflux software is intended to be used to analyze, view, and report ECG data acquired from a variety of ECG sources including single and 3-lead ECG devices. Bioflux software is operated locally in a browser and data is accessed via the users' credentials on the hardware platform running the browser.</p> <p>It will be used by cardiologists, general practitioners, cardiac, or ECG technicians, nurses, monitoring service technicians, and other cardiac related institutions, or care givers, in independent clinical testing facilities, clinics, hospitals, physician's offices, or anywhere a physician or qualified non-physician practitioners deems appropriate</p> <p>Bioflux software does not</p>	<p>Guava II is intended to be used by cardiologists, general practitioners, cardiac or ECG technicians, nurses, monitoring service technicians, and other cardiac related institutions or care givers to store, retrieve, communicate and report ECG and ECG data acquired from a variety of ECG sources including single and multi-lead ECG devices. Guava II is intended to be electronically interfaced, and perform analysis with data transferred from other computer based ECG systems. Guava II includes an algorithm that will analyze the 12 Lead ECG and produce measurements of the ECG recording as well as textual interpretation. The product also includes an automatic analysis and interpretation software library that provides ECG signal processing and analysis on a beat by beat basis, QRS and Ventricular Ectopic Beat detection, QRS feature extraction, interval measurement, heart rate measurement, and rhythm analysis</p>

Category	Identical/ Different	Bioflux	Guava II
		offer diagnosis, or medical alarms. It is intended that competent human intervention be involved before any impact on health occurs. Clinical judgement and experience are used to check and interpret the data.	for up to twelve (12) leads of captured data. Guava II is intended for use in clinics, hospitals, physician’s offices, or anywhere a medical doctor deems appropriate. It is intended that competent human intervention be involved before any impact on health occurs. Clinical judgment and experience are used to check and interpret the data. Guava II may be licensed to other software developers as an ECG viewer for their
The ECG Viewer will meet the EC-11 Standard.	Identical	Yes	Yes
The ECG Viewer will meet the EC-38 Standard.	Identical	Yes	Yes
The ECG Viewer will meet the IEC60601-2-47.	Similar	Yes	Not required at time of submission
The ECG Viewer will meet the IEC60601-2-25 Standard.	Similar	Yes	Not required at time of submission
ECG Viewer will include Beat Caliper measurements in standard ECG intervals (RR, PR, QRS, QT, QTc)	Identical	Yes	Yes
ECG viewer will display ECG traces, as well as speed, gain, and	Identical	Yes	Yes

Category	Identical/ Different	Bioflux	Guava II
filter values.			
ECG viewer will be compatible with web browsers	Similar	Google Chrome and Firefox	Internet Explorer
Software will decode ECGs from a wide range of acoustic devices (using demodulators and FSK analyzers).	Different	Bioflux software does not process ECGs from acoustic devices	Yes
Software will decode ECGs from a wide range of digital devices (using servers).	Different	Bioflux software does not process ECG's from locally connected devices using USB connections	Yes
Software will support import of common ECG data formats (GVX, MIT, RES, SCP)	Similar	Yes	Guava II also accepts data in formats: DAT, CEV, DTX, GVZ, TEL, TMS
Software will provide analysis of ECGs from some specific devices. <ul style="list-style-type: none"> • Heartbeat • Beat Complex 	Different	No	Guava II provides analysis of ECGs from Louvain, and Monebo.
Heart Rate Determination Non-paced	Different	No	Yes
QRS Detection	Different	No	Yes
Non-Paced Arrhythmia Interpretation	Different	No	Yes

Category	Identical/ Different	Bioflux	Guava II
Non-Paced Ventricular Arrhythmia	Different	No	Yes
Interval Measurement	Similar	Yes	Yes
Ventricular Ectopic Beat detection	Different	No	Yes
Beat Caliper, Manual tool to place six vertical lines and adjust beat calipers to mark main points of the QRS complex	Similar	Yes	Yes

VII. PERFORMANCE TESTING

The Bioflux device was tested and complies with AAMI EC11, AAMI EC38, IEC60601-2-25 and IEC60601-2-47 standards. The Bioflux software was verified in both of its operating environments of Firefox and Google Chrome. Verification and validation activities related to the device modification were performed on the applicant device, and the predetermined acceptance criteria were met in all cases. The activities included scenario validations, algorithm confirmation testing, and device functional testing.

VIII. CONCLUSIONS

The testing completed demonstrates that Bioflux Software exhibits comparable technological, and design characteristics to the predicate. Based on those characteristics, the Bioflux Software is substantially equivalent to the predicate device in safety and effectiveness in addition to being intended for the same uses.