July 29, 2020

Biotricity
Spencer Ladow
VP of Engineering
275 Shoreline Drive, Suite 150
Redwood City, California 94065

Re: K201040
Trade/Device Name: Bioflux Software II
Regulation Number: 21 CFR 870.2800
Regulation Name: Medical Magnetic Tape Recorder
Regulatory Class: Class II
Product Code: MWJ
Dated: June 29, 2020
Received: July 2, 2020

Dear Spencer Ladow:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jennifer Shih
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics and Monitoring Devices
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201040

Device Name
Bioflux Software II

Indications for Use *(Describe)*
Bioflux Software II is intended to be used to view and annotate data acquired from diagnostic ECG sources of 1 to 3-leads. Bioflux Software II is operated in a web browser and data is accessed via the users' credentials on the hardware platform running the web browser. It will be used by cardiologists, general practitioners, cardiac, ECG technicians, nurses, monitoring service technicians, and other cardiac related institutions.

Bioflux Software II will be used in independent clinical testing facilities, clinics, hospitals, physician's offices, or anywhere a physician or qualified practitioners deem appropriate.

Bioflux Software II 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.

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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 807.92)

1. SUBMITTER

Biotricity

275 Shoreline Drive, Suite 150

Redwood City CA 94065

1-650-832-1626

Contact: Spencer LaDow

Date Prepared: June 28, 2020

2. DEVICE

Name of Device: Bioflux Software II

Classification Name: Medical Magnetic Tape Recorder

Classification Number: 21 CFR 870.2800

Device Panel: Cardiovascular

Regulatory Class: Class II

Product Code: MWJ

3. PREDICATE DEVICE

Name of Device: Bioflux Software

Classification Name: Medical Magnetic Tape Recorder

Classification Number: 21 CFR 870.2800

Device Panel: Cardiovascular

Regulatory Class: Class II

Product Code: DSH

510(k): K162571

4. DEVICE DESCRIPTION

Bioflux Software II is a browser based ECG viewer software that displays ECG records and provides tools for trained clinicians to annotate (store, retrieve and report) those ECG

recordings. It is utilized by manually opening ECG files of supported formats or through an API that allows for third parties to integrate their devices and directly push ECG files into the viewer.

Bioflux Software II fulfills all of the following:

1. It is a cardiology software product, running locally in a browser.
2. Bioflux Software II operates on 2018 or later versions of Chrome and Firefox browsers.
3. The data can be opened manually or entered via keyboard, mouse or touchscreen where upon it gets opened in the browser for viewing and storage.
4. Information can be displayed on the computer monitor or printed on paper using the web browser.

5. INDICATIONS FOR USE

Bioflux Software II is intended to be used to view and annotate data acquired from diagnostic ECG sources of 1 to 3-leads. Bioflux Software II is operated in a web browser and data is accessed via the users' credentials on the hardware platform running the web browser. It will be used by cardiologists, general practitioners, cardiac, ECG technicians, nurses, monitoring service technicians, and other cardiac related institutions.

Bioflux Software II will be used in independent clinical testing facilities, clinics, hospitals, physician's offices, or anywhere a physician or qualified practitioners deems appropriate.

Bioflux Software II 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.

Indications for Use Comparison Table:

Product/ 510(k) #	BioFlux Software II/ K201040 (under review)	BioFlux Software/ K162571
	Bioflux Software II is intended to be used to view and annotate data acquired from diagnostic ECG sources of 1 to 3-leads. Bioflux Software II is operated in a web browser and data is accessed via the users' credentials on the hardware platform running the web browser. It will be used by cardiologists, general practitioners, cardiac, ECG technicians, nurses, monitoring service technicians, and other cardiac related institutions. Bioflux Software II will be used in independent clinical testing facilities, clinics, hospitals, physician's offices, or anywhere a physician or qualified practitioners deem appropriate. Bioflux Software II does not offer diagnosis, or medical alarms. It is intended	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

	that competent human intervention be involved before any impact on health occurs. Clinical judgement and experience are used to check and interpret the data.	before any impact on health occurs. Clinical judgement and experience are used to check and interpret the data.

6. SUMMARY OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATED DEVICE

The Bioflux Software II is substantially equivalent in intended use and similar technological characteristics of Bioflux Software cleared under K162571.

Category	Bioflux Software II	Bioflux Software
510(k) Number	K201040	K162571
Classification Name	Medical Magnetic Tape Recorder	Medical Magnetic Tape Recorder
Classification Number	21 CFR 870.2800	21 CFR 870.2800
Product Code	MWJ	DSH
Intended Use	View and annotate data acquired from diagnostic ECG sources.	Analyze, view and report data acquired from a variety of ECG sources.
The ECG Viewer will meet the IEC60601-2-47.	Yes	Yes
The ECG Viewer will meet the IEC60601-2-25 Standard.	Yes	Yes
ECG viewer will view and annotate data acquired from diagnostic ECG sources of 1 to 3-leads.	Yes	Yes
ECG viewer will be compatible with web browsers	Yes– Google Chrome and FireFox 2018	Yes- Google Chrome and FireFox 2015
Software will support import of ECG data formats.	Yes- JSON	Yes- GVX, MIT, RES, SCP
Interval Measurement	Yes - manual	Yes - automated
Beat Caliper, Manual tool to place six vertical	Yes	Yes

lines and adjust beat calipers.		
Horizontal Caliper Heart Rate Averaging, Manual tool.	Yes	No - Bioflux software does not have this manual horizontal caliper.

7. PERFORMANCE TESTING

The Bioflux Software II device was tested and complies with AAMI EC11, AAMI EC38, IEC60601-2-25 and IEC60601-2-47 standards. The Bioflux Software II 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, beat marker confirmation testing, and device functional testing.

8. CONCLUSIONS

The conclusions drawn from the indications for use and testing demonstrates that Bioflux Software II exhibits comparable indications for use, technological, and design characteristics to the predicate (Bioflux Software). Based on this, the Bioflux Software II is as safe, and effective, and performs as well as the legally marketed device predicate. The Bioflux Software II is substantially equivalent to the predicate device.