January 19, 2022

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

Re: K211709
Trade/Device Name: Biotres
Regulation Number: 21 CFR 870.2800
Regulation Name: Medical Magnetic Tape Recorder
Regulatory Class: Class II
Product Code: MWJ
Dated: December 20, 2021
Received: December 22, 2021

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 Kozen
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211709

Device Name
Biotres

Indications for Use *(Describe)*

The Biotres is indicated for use on adult patients 18 years or older who may be asymptomatic or who suffer from transient symptoms such as palpitations, shortness of breath, dizziness, light headedness, pre-syncope, syncope, fatigue, chest pain and/or anxiety and may require cardiac recording on a continuous basis for up to 30 days. The signal acquired by the Biotres is not intended and should not be used for automated or semi-automated analysis.

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)

Date Prepared: January 10, 2022

I. SUBMITTER

Biotricity
275 Shoreline Drive, Suite 150
Redwood City CA 94065
Contact Person: Spencer LaDow
sladow@biotricity.com
Phone: 585-414-7407

II. DEVICE

Name of Device:	Biotres
Classification Regulation:	21 CFR§870.2800
Common Name:	Medical Magnetic Tape Recorder
Device Panel:	Cardiovascular
Regulatory Class:	Class II
Product Code:	MWJ Electrocardiograph, Ambulatory (without Analysis)

III. PREDICATE DEVICE

The ePatch (Braemar Manufacturing, LLC) was cleared under K171410.

Name of Device:	ePatch
Classification Regulation:	21 CFR§870.2800
Common Name:	Medical Magnetic Tape Recorder
Device Panel:	Cardiovascular
Regulatory Class:	Class II
Product Code:	DSH

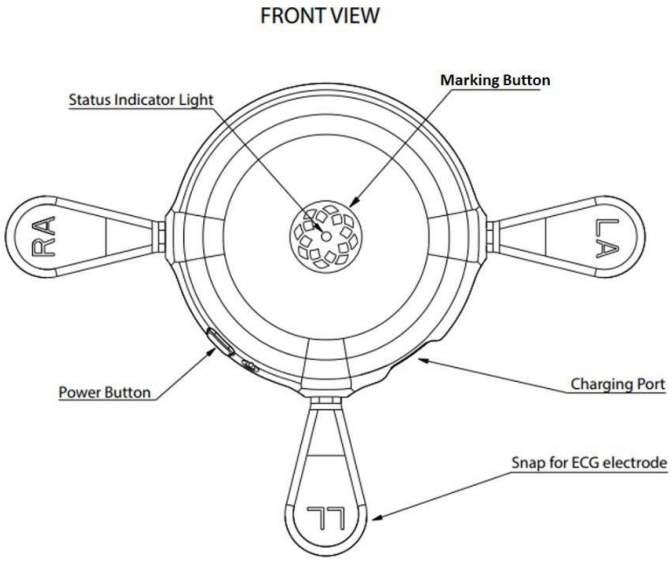
IV. DEVICE DESCRIPTION

The Biotres system consists of 1) the Biotres Recorder, 2) a dedicated Biotres AC wall charger, 3) Biotres Gateway application for use on mobile devices using Android or iOS, and 4) Biotres Configured Secure Server.

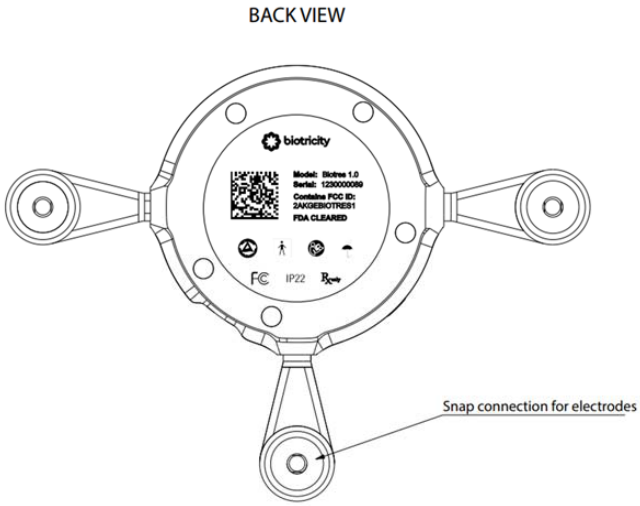
Biotres Recorder

The Biotres Recorder is an ECG recording only device and does not include ECG analysis, an ECG viewer/ECG display, alarms and is not a real time ECG monitor. The Biotres recorder is a small, lightweight, ambulatory, reusable 3 channel ECG recorder that is placed on the center of the chest (Reference Below).

Biotres Recorder – Front View



Biotres Recorder – Back View



The Biotres Recorder has two buttons: 1) power button and 2) patient event marking button. The patient is to push the patient event marking button when the patient is feeling symptoms such as palpitations, shortness of breath, dizziness, light headedness, pre-syncope, syncope, fatigue, chest pain and/or anxiety. There is an LED "status indicator light" in the middle of the patient event marking button that provides recorder status indications when powering on, electrodes are disconnected, low battery, charging, fully charged, encountered internal error, acknowledgment of the patient event marking button, and study not engaged/start/running/paused/completed state.

The Biotres Recorder attaches to the patient's chest through three standard commercially available ECG electrodes (not include with the system) supplied by a clinic or a monitoring center. Biotres includes a Bluetooth modem to communicate with the Biotres Configured Secure Server through the Biotres Gateway Application. The Biotres Recorder integrated memory can store up to 30-days of ECG data. This data can be uploaded by the clinician to the Biotres Configured Secure Server.

Biotres AC Wall Charger

The dedicated Biotres AC Wall charger is used to charge the Biotres Recorder daily when disconnected from the patient.

Biotres Gateway Application

The ECG recorded data is transferred via the Biotres Gateway App (Downloaded from the appropriate app store for iOS or Android respectively) via a Bluetooth connection and subsequently to the Biotres Configured Secure Server. Clinicians can use the Biotres Gateway Application using their privileged login credentials to connect Biotres Recorders to the Biotres Configured Secure Server so that patient studies may be started and completed. The Biotres Gateway Application can be used by the patient once registered (nonprivileged login credentials) and the patient can use the application to monitor the status indicators of the Biotres Recorder and to enter symptoms if the Event Marking Button is pressed on the recorder. The ECG recorded data from the Biotres Recorder can be transferred, by the clinician, from the Biotres Configured Secure Server when the recorder is connected to the Biotres Gateway App at the end of a patient study.

Biotres Secure Server

The Biotres Configured Secure Server is an SFTP server that is configured to work with the Biotres System. The server enables the Clinician, through secured login, to command the Biotres Recorder (e.g. initiate ECG data collection) and to access uploaded MIT16 ECG data recordings when the ECG data collection is complete. Biotres does not provide the patient or clinician with diagnostic or interpretive statements based on the ECG data. Diagnosis and interpretation of ECG data is dependent upon the medical advice and guidance provided by a physician or trained healthcare professional. The Biotres is for home use and not for use in the hospital. Clinical judgment and experience are used to check and interpret the data.

V. INDICATIONS FOR USE

The Biotres is indicated for use on adult patients 18 years or older who may be asymptomatic or who suffer from transient symptoms such as palpitations, shortness of breath, dizziness, light headedness, pre-syncope, syncope, fatigue, chest pain and/or anxiety and may require cardiac recording on a continuous basis for up to 30 days. The signal acquired by the Biotres is not intended and should not be used for automated or semi-automated analysis.

VI. CONTRAINDICATIONS FOR USE

The Biotres device is not intended for use under the following conditions:

- Patients with potentially life-threatening arrhythmias who require inpatient monitoring.
- Patients who the attending physician thinks should be hospitalized.
- Infants weighing less than 10 kg. (22 lbs.).
- Patients with implanted pacemakers.
- Defibrillator Use.

VII. SUMMARY OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Category	Identical/ Different	Biotres	ePatch
510(k) Number		K211709	K171410
Classification Name	Identical	Medical Magnetic Tape Recorder	Medical Magnetic Tape Recorder
Product Code	Similar	MWJ	DSH
Intended Use	Similar	The Biotres is indicated for use on adult patients 18 years or older who may be asymptomatic or who suffer from transient symptoms such as palpitations, shortness of breath, dizziness, light headedness, pre-syncope, syncope, fatigue, chest pain and/or anxiety and may require cardiac recording on a continuous basis for up to 30 days. The signal acquired by the Biotres is not intended and should not be used for automated or semi-automated analysis.	ePatch® is indicated for use on patients who may be asymptomatic or who may suffer from transient symptoms such as palpitations, shortness of breath, dizziness, light headedness, pre-syncope, syncope, fatigue, chest pain and/or anxiety. The ePatch® is intended for use by adolescents 18-21 and adults.
Defibrillator Protection	Similar	Not Defibrillator Proof, 8.5.5.2 of IEC 60601-1 passed	Not Defibrillator Proof
Wear Time	Different	Up to 30 Days	Up to 5 days
Recording Format	Identical	Continuous	Continuous
Delivered device includes	Similar	-3 lead ECG monitor -internal rechargeable battery -Wall Battery charger	ePatch monitor Battery Sensor Patch Skin prep kit
Monitor functional blocks	Similar	Analog ECG front end, MCU, Flash data storage, BLE modem for data transmission, LED indicator, and	Analog ECG front end, Accelerometer, MCU, Flash data storage, USB cable for data transmission,

Category	Identical/ Different	Biotres	ePatch
		Record button	LED indicator, and Record button
The App:	Similar	Mobile App, iOS, Android	PC based
The server:	Similar	Facilitate data communication with the Biotres device, provide data storage, and present the data for evaluation by a medical professional	Facilitate data communication with the ePatch device, provide data storage, and present the data for evaluation by a medical professional
Device form factor	Identical	Small, lightweight body worn ambulatory cardiac monitors.	Small, lightweight body worn ambulatory cardiac monitors.
Wireless technology used to transmit data to server	Different	Yes	No
Device is battery powered by a rechargeable Li-Ion battery	Identical	Yes	Yes
Using an app, can adjust device programming parameters such as pre-post recording times and auto-triggering configuration.	Similar	Yes, app is android or IOS based	Yes, app is PC based
Devices have Record button for manual event recordings and a user led to indicate device status and mode of operation.	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 for battery charging cannot be connected during ECG recording	Yes, used for data download and communication, battery charging cannot be connected during ECG recording

VIII. 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.
- 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 Biotres system can continuously record ECG signal, store ECG data in the device memory, and transmit manual activated event recordings to the server via Bluetooth Biotres Gateway app connection for evaluation by a medical professional. Test results verify that all requirements were met and that the Biotres System performs as designed.

IX. CONCLUSION

The analysis of the differences between Biotres and the predicate device does not raise new questions of safety and effectiveness. Based on device performance test results, Biotricity determined that the Biotres system performed within its design specifications and is considered to be substantially equivalent to the predicate device.