October 30, 2020

eCordum, Inc.
% Becky Ditty
Consultant
Biologics Consulting
1555 King St, Suite 300
Alexandria, Virginia 22314

Re: K193296
Trade/Device Name: eCordum Cardiac Monitor (eCordum CM)
Regulation Number: 21 CFR 870.2920
Regulation Name: Telephone electrocardiograph transmitter and receiver
Regulatory Class: Class II
Product Code: DXH
Dated: November 26, 2019
Received: November 27, 2019

Dear Becky Ditty:

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,

for

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193296

Device Name
eCordum™ Cardiac Monitor (eCordum™ CM)

Indications for Use *(Describe)*
The eCordum™ Cardiac Monitor is intended to record, transfer and store single-channel electrocardiogram (ECG) data via Bluetooth transmission to Bluetooth enabled devices. The monitor is intended for use by healthcare professionals, patients with known or suspected heart conditions and health conscious individuals. The ECG data is intended to supplement other patient data and is not intended for automated analysis. The device has not been tested and it is not intended for pediatric use.

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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K193296 510(k) Summary

1. Submission Sponsor

eCordum, Inc.
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3. Date Prepared

November 26, 2019

4. Device Identification

Trade/Proprietary Name:	eCordum™ Cardiac Monitor (eCordum™ CM)
Common/Usual Name:	Transmitters and receivers, electrocardiograph, telephone
Regulation Name:	Telephone electrocardiograph transmitter and receiver
Classification Regulation:	21 CFR§870.2920
Product Codes:	DXH
Device Class:	II
Classification Panel:	Cardiovascular

5. Legally Marketed Predicate Device(s)

K121197 BodyGuardian System manufactured by Preventice Solutions

6. Device Description

The eCordum™ Cardiac Monitor (eCordum™ CM) is intended to record, transfer and store single-channel electrocardiogram (ECG) data via Bluetooth transmission to Bluetooth enabled devices. The monitor is intended for use by healthcare professionals, patients with known or suspected heart conditions and health conscious individuals. The device has not been tested and it is not intended for pediatric use.

The eCordum™ CM device is powered by a replaceable battery and has two interchangeable attachable covers with respective ECG electrodes for long-term ECG recording. The Wearable Unit for long-term recording is used with two standard disposable Off-The-Shelf (OTS) ECG electrodes. For long term recording ECG data is obtained by attaching the device to user's chest using OTS ECG electrodes. Long-term recordings provide a single channel ECG signal. During recording the device collects and encrypts ECG data in the storage media for unidirectional transmission to a Bluetooth enabled device.

7. Indication for Use Statement

The eCordum™ Cardiac Monitor is intended to record, transfer and store single-channel electrocardiogram (ECG) data via Bluetooth transmission to Bluetooth enabled devices. The monitor is intended for use by healthcare professionals, patients with known or suspected heart conditions and health conscious individuals. The ECG data is intended to supplement other patient data and is not intended for automated analysis. The device has not been tested and it is not intended for pediatric use.

8. Substantial Equivalence Discussion

Comparison of Indications

Table 1 compares the indications for use of the subject device with the indications for use of the two predicate devices.

Table 1: Comparison of Indications for Use

eCordum CM (K193296)	**Preventice (K121197)**
The eCordum™ Cardiac Monitor is intended to record, transfer and store single-channel electrocardiogram (ECG) data via Bluetooth transmission to Bluetooth enabled devices. The monitor is intended for use by healthcare professionals, patients with known or suspected heart conditions and health conscious individuals. The ECG data is intended to supplement other patient data and is not intended for automated analysis. The device has not been tested and it is not intended for pediatric use.	The BodyGuardian System detects and monitors non-lethal cardiac arrhythmias in ambulatory patients, when prescribed by a physician or other qualified healthcare professional. The BodyGuardian System continuously records, stores and periodically transmits the following physiological data to a remote computer server for up to 30 days at a time: • ECG • Heart rate (including HR variability and HR reliability) • Respiration rate • Activity

The subject device and the predicate devices have the same fundamental intended use, namely to record, store and transfer ECGs. The subject eCordum device does NOT perform any arrhythmia detection, and does not detect heart rate, respiration rate nor activity.

In regard to the eCordum wearable, the subject device and the predicate Preventice device are both intended for prescription use only.

These differences do not raise different questions of safety and effectiveness, and thus do not constitute a new intended use.

Comparison of Technological Comparison

Table 2 provides a detailed comparison between the subject device and the predicate devices.

Table 2: Device Comparison Table

	Proposed eCordum CM Device	Predicate Preventice Wearable ECG Monitor
510(k) Number	K193296	K121197
Applicant	eCordum, Inc.	Preventice
Device Name	eCordum™ CM	Preventice BodyGuardian Device
Classification Regulation	21 CFR§870.2920	21 CFR§870.1025
Product Code	DXH	DSI
Rx or OTC	RX for wearable option	RX
Intended Use	Ambulatory	Ambulatory
Alarm	No	No
Adult/Pediatric	Adult	Adult
Electrodes	Attachable standard ambulatory OTS electrodes with conductive gel.	Attachable standard ambulatory OTS electrodes with conductive gel.

	Proposed eCordum CM Device	Predicate Preventice Wearable ECG Monitor
Single Use/Reusable	Disposable ambulatory OTS electrodes.	Disposable ambulatory OTS electrodes.
ECG and Events Storage	Transmit ECG data to a Bluetooth enabled device.	Stores and periodically transmits events and ECG data to remote server via a mobile device when internet is available.
Real time ECG View	No	No
Arrhythmia Detection	No	Yes
Sampling Rate	250 Hz	250 Hz
Application/Wear	Chest for ambulatory OTS electrodes.	Chest for ambulatory OTS electrodes.
User Interface	Automatic turn on upon skin contact Mobile app	Same
Connection	Class II Bluetooth	Class II Bluetooth
Power Supply	Replaceable battery	Single use rechargeable battery

The eCordum™ CM has a same intended use and similar technological characteristics performance as the predicate devices. The subject device has been tested and shown to comply with IEC 60601-2-47. The results of firmware testing showed that eCordum CM device meet all requirements and specifications as described in the Software Validation and Verification protocol and reports.

9. Performance Data

The eCordum™ Cardiac Monitor meets all the requirements for overall design, biocompatibility, electrical, EMC safety and cybersecurity protection. The eCordum™ Cardiac Monitor passed all testing and supports the claims of substantial equivalence and safe operation.

Biocompatibility

A biocompatibility assessment for patient contacting materials was performed in accordance with ISO 10993-1:2009. All biocompatibility testing passed.

Software Documentation

Software verification and validation testing was conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices". Verification of the eCordum™ Cardiac Monitor was conducted to ensure that the product works as designed. Validation was conducted to check the design and performance of the product.

EMC and Electrical Safety

The eCordum™ CM was assessed for conformity with the relevant requirements of the following standards and found to comply:

- ANSI/AAMI ES 60601-1:2005/(R) 2012 and A1:2012, C1:2009/(R) 2012 and A2:2010/(R) 2012
- IEC 60601-1-2:2014 (Fourth Edition)

Bench Testing

Bench testing was done to support device performance and substantial equivalence. Testing demonstrating that the eCordum™ Cardiac Monitor complies with ANSI/AAMI/IEC 60601-2-47:2012 (60601-2-47); Medical electrical equipment – Part 2-47. The eCordum™ Cardiac Monitor met all the requirements for overall design confirming that design output meets design inputs and specifications.

10. Statement of Substantial Equivalence

The eCordum™ Cardiac Monitor is substantially equivalent to predicate device. The eCordum™ Cardiac Monitor has the same intended use and the same technological characteristics as the previously cleared predicate device, BodyGuardian monitor by Preventice. The new device (eCordum™ Cardiac Monitor) does not raise different questions regarding its safety and effectiveness as compared to the predicate device.