May 7, 2024

Kestra Medical Technologies, Inc.
Jay Wiese
Sr. Regulatory Affairs Specialist
3933 Lake Washington Boulevard NE
Suite 200
Kirkland, Washington 98033

Re: K233864
Trade/Device Name: ASSURE Wearable ECG
Regulation Number: 21 CFR 870.2800
Regulation Name: Medical Magnetic Tape Recorder
Regulatory Class: Class II
Product Code: MWJ, DXH
Dated: April 9, 2024
Received: April 9, 2024

Dear Jay Wiese:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 W. Shih -S

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.

Submission Number *(if known)*

K233864

Device Name

ASSURE Wearable ECG (80553-001)

Indications for Use *(Describe)*

The ASSURE Wearable ECG is indicated for adult patients who have been prescribed this device by a medical professional, who were previously prescribed the ASSURE WCD system, and who may be asymptomatic or who may suffer from transient symptoms such as palpitations, shortness of breath, dizziness, light-headedness, presyncope, syncope, fatigue, or anxiety. The signal acquired by the ASSURE Wearable ECG is not intended and should not be used for automated or semi-automated analysis. The device does not deliver any therapy, administer any drugs, provide interpretive or diagnostic statements, or provide for any life support.

The ASSURE Wearable ECG is contraindicated for use in patients with an active implantable pacemaker or defibrillator.

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.

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510(k) Summary (K233864)

Date Prepared: April 9, 2024

I. General Information

Applicant:
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Contact Person:
Bev Magrane
VP, Quality and Regulatory Affairs
Email: beverly.magrane@kestramedical.com

II. Device Information

Trade Name:
ASSURE Wearable ECG

Generic/Common Name:

Classification Regulation:	21 CFR 870.2800
Classification Name:	Medical Magnetic Tape Recorder
Regulatory Class:	Class II
Product Codes:	MWJ Electrocardiograph, Ambulatory (Without Analysis) DXH Transmitters and Receivers, Electrocardiograph, Telephone

III. Predicate Devices

The following predicate devices have been selected:

Primary Predicate Device:	Biotricity Biotres system
Predicate Clearance	K211709 (19 Jan 2022)
Classification Regulation:	21 CFR 870.2800
Classification Name:	Medical Magnetic Tape Recorder
Regulatory Class:	Class II
Product Code:	MWJ Electrocardiograph, Ambulatory (Without Analysis)
Secondary Predicate Device:	Biotricity Bioflux system
Predicate Clearance	K172311 (15 Dec 2017)
Classification Regulation:	21 CFR 870.2920
Classification Name:	Telephone Electrocardiograph Transmitter and Receiver
Regulatory Class:	Class II
Product Code:	DXH Transmitters and Receivers, Electrocardiograph, Telephone

IV. Indications for Use

The ASSURE Wearable ECG is indicated for adult patients who have been prescribed this device by a medical professional, who were previously prescribed the ASSURE WCD system, and who may be asymptomatic or who may suffer from transient symptoms such as palpitations, shortness of breath, dizziness, light-headedness, presyncope, syncope, fatigue, or anxiety. The signal acquired by the ASSURE Wearable ECG is

not intended and should not be used for automated or semi-automated analysis. The device does not deliver any therapy, administer any drugs, provide interpretive or diagnostic statements or provide for any life support.

The ASSURE Wearable ECG is contraindicated for use in patients with an active implantable pacemaker or defibrillator.

V. Intended Use

The ASSURE Wearable ECG continuously monitors heart rate information. Event data, which is automatically stored for low and high heart rates and patient-triggered events, is intended to aid medical professionals as they monitor various clinical conditions, events, and trends. The ASSURE Wearable ECG is intended for use by a patient during their normal daily activities primarily in the home or community setting, but also hospitals, medical clinics, healthcare facilities and transport.

VI. Device Description

The ASSURE Wearable ECG is a reusable, ambulatory electrocardiography-based, cardiac- and physiologic-monitoring, medical-electrical system whose intended purpose is to inform clinical management of options for diagnosing, monitoring and/or mitigating cardiac conditions after patient's improvement following ASSURE® Wearable Cardioverter Defibrillator (WCD) prescriptive use. The system utilizes the same five-electrode SensorFit™ Garment worn previously with the WCD prescription. The system continuously records ECG data and upon detection, it identifies and records episodes as high and low heart rate, as well as patient-triggered events. The system utilizes the same algorithm detection and episode reporting software marketed in the ASSURE WCD with high (Tachy) and low (Brady) capture for later transmission to the medical professional for interpretation. The system captures and stores ECG episodes, and non-ECG patient activity and wear information to be displayed and reported in counters and trends. Recorded events include ECG waveforms and reports identifying high and low heart rates, as well as patient-triggered events. The system uses a 3-axis accelerometer to monitor non-ECG patient activity (steps and wear time).

The ASSURE Wearable ECG event reports do not contain diagnostic interpretation. The reported events are provided for review by the prescriber to assist in diagnosis and/or prognosis of the recently transitioned WCD patient and to assess care options based on the healthcare professional's judgment and experience.

The ASSURE Wearable Cardiac ECG is a prescription use device. The ASSURE Wearable ECG is intended for use by a patient during their normal daily activities primarily in the home or community setting, but also hospitals, medical clinics, healthcare facilities and transport. The device is non-invasive, reusable, and intended to be used on one patient at a time.

The Wearable Cardiac ECG System is comprised of the following reusable patient-worn components:

- Monitor Cable Assembly – Houses the primary electronics, embedded application software, communication modules, and ECG signal acquisition hardware. It includes a Hub, Alert Button and Battery Connector.
- Hub – Physical housing for the primary Wearable ECG electronics and 3-axis accelerometer. The Hub provides a means for connecting the Monitor Cable to the Garment.
- Alert Button – Provides audio, tones and voice prompts as well as vibratory alerts and a button for the user to provide input.
- Battery Pack – Rechargeable Lithium-Ion battery.
- SensorFit™ Garment – This is the same PMA-approved (P200037) garment previously worn with the WCD and fitted according to body size and body style. The Garment includes built-in ECG electrodes and provides a method of affixing the Hub, Alert Button, and Battery Pack for proper placement during operation.
- Charger – Medical-grade AC-DC power adaptor and USB-C power cable.

VII. Comparison of Technological Characteristics with Predicate Device

The subject ASSURE Wearable ECG has the same intended use as the predicate devices. The differences in the technological characteristics between the subject and predicate devices do not raise any issues of safety or effectiveness as the fundamental scientific technology and intended use is unchanged.

The ASSURE Wearable ECG is considered substantially equivalent to the predicate devices. A comparison table outlining the similarities and differences between the subject device and the predicate devices is provided in the Summary Table below.

Category	**Wearable ECG (subject)**	**Biotres (predicate) K211709**	**Bioflux (secondary) K172311**
Indications for Use	The ASSURE Wearable ECG is indicated for adult patients who have been prescribed this device by a medical professional, who were previously prescribed the ASSURE WCD system, and who may be asymptomatic or who may suffer from transient symptoms such as palpitations, shortness of breath, dizziness, light-headedness, presyncope, syncope, fatigue, or anxiety. The signal acquired by the Wearable ECG is not intended and should not be used for automated or semi-automated analysis. The device does not deliver any therapy, administer any drugs, provide interpretive or diagnostic statements or provide for any life support.	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.	The bioflux 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 bioflux 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. bioflux is for prescription use only.
Classification Name	Recorder, Magnetic Tape, Medical	Recorder, Magnetic Tape, Medical	Telephone electrocardiograph transmitter and receiver
Product Code	MWJ, DXH	MWJ	DXH

Category	Wearable ECG (subject)	Biotres (predicate) K211709	Bioflux (secondary) K172311
Defibrillator Protection	The ECG Electrodes in the WCD-approved Garment are classified as defibrillation-proof applied parts.	Not Defibrillator Proof, 8.5.5.2 of IEC 60601-1 passed	
Wear Time	Up to 30 Days	Up to 30 Days	Up to 30 Days
Recording Format	Continuously monitors ECG and activity data. Data is auto-triggered for events such as Bradycardia and Tachycardia, as identified by an embedded arrhythmia detection algorithm; and stored as low and high heart rate episodes and patient-triggered events	Continuous	Captures patient-activated and auto-triggered events such as Bradycardia, Tachycardia, pause and Atrial Fibrillation as identified by an embedded arrhythmia detection algorithm
Delivered device includes	ECG monitor with 5-electrode WCD-supplied garment Internal rechargeable battery Wall Battery charger	-3 lead ECG monitor -internal rechargeable battery -Wall Battery charger	Device has at least 2 ECG channels and 3-lead electrodes
Monitor functional blocks	Analog ECG front end, accelerometer, MCU, eMMC data storage, BLE modem for data transmission, LED indicator, and event record button	Analog ECG front end, MCU, Flash data storage, BLE modem for data transmission, LED indicator, and Record button	Analog ECG front end, MCU, Flash data storage, RF modem for data transmission, LCD screen, and Record button
Data transfer	Bluetooth for transfer of patient data by mobile data client to a Wi-Fi-connected server	Mobile App, iOS, Android	Data can be delivered to the server wirelessly via mobile network
Server	Subsequent access to ECG display and episode report viewer for evaluation by prescribing medical professional	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 Bioflux device, provide data storage, and present the data for evaluation by a medical professional
Device form factor	Utilizes Kestra PMA-approved WCD garment electrodes	Small, lightweight body worn ambulatory cardiac monitors	Small, lightweight body worn ambulatory cardiac monitors

Category	Wearable ECG (subject)	Biotres (predicate) K211709	Bioflux (secondary) K172311
Wireless technology used to transmit data to server	Yes	Yes	Data is delivered to the server wirelessly via mobile cellular dedicated network connection
Power	Device is battery powered by a rechargeable Li-Ion battery	Device is battery powered by a rechargeable Li-Ion battery	Device is battery powered by a rechargeable Li-Ion battery
Device Program Parameters	ASSURE Wearable ECG has no user-programmable functions or features	Using an Android or IOS based app, clinician can adjust device programming parameters such as pre-post recording times and auto-triggering configuration	A medical professional, using the server, can adjust and program the device configuration and auto-triggering parameters
Monitor Multiple Parameters	ECG signal, high and low heart rate and accelerometer-based patient data (steps and wear time)	No (ECG only)	Captures patient activated and auto-triggered events such as Bradycardia, Tachycardia, pause and Atrial Fibrillation as identified by an embedded arrhythmia detection algorithm
Manual Event Recording	Alert button for patient-triggered event recordings and visual, audio and haptic modes of alerting patient to device status	Devices have Record button for manual event recordings and a user LED to indicate device status and mode of operation.	Devices have Record button for manual event recordings and a user LED to indicate device status and mode of operation.
Prescriber Review	The ECG recorded data from the ASSURE Wearable ECG is transferred to the clinician from the Kestra Secure Server when the device is connected to the server at the end of a patient study	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.	Automatically delivers the recorded cardiac activity to the server where it is presented and can be reviewed by a medical professional

VIII. Performance Data

Safety and performance of the subject ASSURE Wearable ECG system has been evaluated and verified in accordance with design specifications and to support a determination of substantial equivalence to the predicate device. Because the device is designed and intended to monitor low-risk patients using proprietary algorithm detection software developed for the ASSURE Wearable Cardioverter Defibrillator, it intentionally does not meet all performance clauses of IEC 60601-2-47:2015 that are associated with diagnostic ECG.

The following performance and safety tests have passed successfully:

Recognition Number	*Number*	*Document Description (Title)*
19-49	IEC 60601-1:2005+A1:2012+A2:2020	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (Edition 3.2)
19-36	IEC 60601-1-2:2014+A1:2020	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
19-38	IEC 60601-1-11:2015+A1:2021	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
3-155	IEC 60601-2-47:2015	Medical electrical equipment - Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems
2-258	ISO 10993-1:2018	Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process
19-11	UL 2054:2004(R2011)	Standard for Household and Commercial Batteries, 2nd Edition
19-33	IEC 62133-2:2017	Secondary cells and batteries containing alkaline or other non-acid electrolytes — Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications, Part 2: Lithium systems (IEC 62133-2:2017)
19-30	AIM 7351731:2017	Medical Electrical Equipment and System Electromagnetic Immunity Test for Exposure to Radio Frequency Identification Readers – An AIM Standard (Rev. 2.00)

Bench test results verify that the ASSURE Wearable ECG system can continuously monitor ECG signal, store ECG event data in the device memory, and transmit recorded data to a Kestra display server for clinician review.

IX. Conclusion

Based on a review of the test results and a comparison to the predicate devices characteristics and known specifications, the results show that the ASSURE Wearable ECG is substantially equivalent to the predicate device.