March 22, 2023

Icentia Inc.
% Christina Henza
Regulatory Affairs
Ultra Lifescience Solutions Inc
2811 Milton Ave #409
Janesville, Wisconsin 53545

Re: K223049
Trade/Device Name: CardioSTAT® ECG Test Solution
Regulation Number: 21 CFR 870.2800
Regulation Name: Medical magnetic tape recorder
Regulatory Class: Class II
Product Code: DSH, DQK
Dated: February 21, 2023
Received: February 21, 2023

Dear Christina Henza:

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 Shruti N. Mistry -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.

510(k) Number *(if known)*
K223049

Device Name
CardioSTAT ECG Test Solution

Indications for Use *(Describe)*
The CardioSTAT ECG Test Solution is intended to capture, analyze, and report symptomatic and/or continuous ECG information for long-term ambulatory monitoring (up to 14 days). It is indicated for use on adult patients who may be asymptomatic or who may suffer from transient symptoms, such as palpitations, shortness of breath, dizziness, lightheadedness, presyncope, syncope, fatigue, or anxiety. The reported ECG metrics include single-lead analysis on a beat by beat basis, heart rate measurement and rhythm annotation. The report does not contain diagnostic interpretation; the report is provided for review to the intended user to render a diagnosis based on clinical judgment and experience.

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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510(k) Summary

(21 CFR 807.92)

Date Prepared: March 20, 2023

5.1. GENERAL INFORMATION

Submitter:
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5.2. DEVICE INFORMATION

Trade Name: CardioSTAT® ECG Test Solution
Common Name: Single-Use Ambulatory Electrocardiogram (ECG) Recorder
Regulatory Class: Class II
Classification Name:
Medical Magnetic Tape Recorder [21CFR§870.2800],
Programmable Diagnostic Computer [21CFR§870.1425]
Product Code: DSH, DQK
Special Controls: At this time, no special controls have been issued for devices with product codes DSH, DQK.

5.3. PREDICATE DEVICE(S)

Zio® SkyRunner (SR) Electrocardiogram (ECG) Monitoring Service, [K143513]
Reference device: Carnation™ Ambulatory Monitor Model 3000, [K143067]
The predicates have not been subject to a design-related recall.

5.4. INDICATIONS FOR USE

System Indication for USE

The CardioSTAT® ECG Test Solution is intended to capture, analyze, and report symptomatic and/or continuous ECG information for long-term ambulatory monitoring (up to 14 days). It is indicated for use on adult patients who may be asymptomatic or who may suffer from transient symptoms, such as palpitations, shortness of breath, dizziness, lightheadedness, presyncope, syncope, fatigue, or anxiety. The reported ECG metrics include single-lead analysis on a beat by beat basis, heart rate measurement and rhythm annotation. The report does not contain diagnostic interpretation; the report

is provided for review to the intended user to render a diagnosis based on clinical judgment and experience.

5.5. DEVICE DESCRIPTION

The CardioSTAT® ECG Test Solution is a complete by prescription-only system for continuous ambulatory collection of ECG single-channel data for up to 14 days, followed by analysis and reporting of collected data. The CardioSTAT® ECG Test Solution is composed of two major components: (1) CardioSTAT® ECG Recorder and (2) ECG Analysis and Reporting Tool (EART) .

The CardioSTAT® ECG Recorder (1) is a nonsterile, non-invasive, and single-patient-use recorder worn on the patient's torso that provides a continuous, single-channel, ECG recording for up to 14 days. The Recorder snaps onto two off-the-shelf FDA-cleared long-term monitoring electrodes on which OFIX® adhesive tape is applied to ensure long-term adherence to the patient. After the prescribed recording duration, the device is taken off by the patient and mailed to the data analysis center for analysis where data is analyzed by Certified Cardiographic Technicians (CCT) using (2) ECG Analysis and Reporting Tool (EART). The EART is intended for use only by trained technicians. A clinical report is then sent to the physician. The report does not contain diagnostic interpretation; the reported analysis is provided for review by the physician to render a diagnosis based on clinical judgment and experience.

A home use kit (CardioSTAT® Home Application) is also offered which includes all required devices to allow for remote prescription and home application of the CardioSTAT® recorder. The included devices (surgical razor, alcohol prep pad, electrodes, OFIX® tape) outside of this submission are currently available on the market.

The CardioSTAT® device is not designed to record ECG signals suitable to identify ST segment shifts and the EART software is not designed to detect or measure ST segment shifts.

The ECG signal collected by the CardioSTAT® ECG Test Solution is not intended for automated analysis other than beat and noise detection.

The ECG signal collected by the CardioSTAT® ECG Test Solution is not intended for third party ECG analysis systems.

The CardioSTAT® recorder is not a real-time device and all clinical data is reviewed after the device has been returned to Icentia.

The CardioSTAT® ECG Test Solution software provides automated detection of beats and noise only. All other classifications, rhythms and anomalies must be annotated by hand by the user in the EART software. Detections of beats and noise must be verified and confirmed by the user, or manually corrected with their respective annotation tools.

5.6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The proposed (subject device) CardioSTAT® Electrocardiogram (ECG) Test Solution is substantially equivalent to the primary predicate device 'Zio® SR ECG Monitoring Service (K143513 cleared on 06/19/2015)' with the reference device Carnation™ Ambulatory Monitor Model 3000 (CAM) (K143067 cleared on 12/22/2014) to support the difference in placement and the allowance for the option of user upload or manufacturer service, based on availability and user preference.

The predicate and reference devices are class II legally marketed devices as shown by the associated 510(k) numbers and clearance dates. All of the devices use the same main product code, DSH; Medical magnetic tape recorder. The subject device and the predicate use a secondary product code of DQK (Programmable diagnostic computer).

The regulation intended use covers the proposed and predicate devices. Comparison of the predicate device indications shows 6 main elements: (1) functionality, (2) duration, (3) demographics, (4) recording type, (5) reported metrics, and (6) report type. For the reference device, some of this information was not included in the indication statement so the relevant information was extracted from the IFU, brochure, and sample report to make the comparison.

All of the devices have the same primary technological characteristics. The CardioSTAT® ECG Test Solution is composed of two major components: (A) CardioSTAT® ECG Recorder and (B) ECG Analysis and Reporting Tool (EART) . Both the predicate (Zio Recorder & Zio ECG Utilization Service (ZEUS) and reference device (CAM & BDxCONNECT) have similar main components.

The main technological differences include:

i. Separation of device and electrodes raise a question concerning electrode performance. Electrode performance is standardized (ANSI/AAMI EC12:2000 (R2015) Disposable ECG Electrodes) and all of these electrodes are compliant to the standard. The primary predicate (Zio) has integrated the two accessories of the subject device (OFIX® & 3M electrodes) and the reference device has taken integration of the devices further incorporating the battery into the electrode to create a "battrode", however the function and performance of the components remains equivalent based on compliance with standard requirements. This question of electrode performance applies to the new device and the predicate / reference devices equally and is thus not considered a different or new question of safety and efficacy.

ii. Electrode application in vertical and horizontal positions raises a question of signal acquisition quality. The reference device is presented to support technological differences related to vertical placement. Clinical data in the form of literature and International Post Market Surveillance data is included in support of the horizontal application. This question of signal acquisition quality applies to the new device and the predicate / reference devices equally and is thus not considered a different or new question of safety and efficacy.

iii. Report contents raise a question of whether the report includes all information required by the clinician for diagnosis. The full ECG signal data is made available to the Certified Cardiographic Technicians in all three devices. The clinical report of all three devices contain the specifically identified content by

the CCT. This question of report content applies to the new device and the predicate / reference devices equally and is thus not considered a different or new question of safety and efficacy.

The identified questions of safety and efficacy listed above apply to both the new device and the predicate/reference devices and so the new device does not raise different or new questions of safety and efficacy. Therefore, the proposed (subject device) CardioSTAT® Electrocardiogram (ECG) Test Solution meets substantial equivalence requirements with regards to the legally marketed predicate device Zio® SR ECG Monitoring Service (K143513 cleared on 06/19/2015) and reference device Carnation™ Ambulatory Monitor Model 3000 (CAM) (K143067 cleared on 12/22/2014)

5.7. PERFORMANCE DATA

The CardioSTAT® ECG Test Solution has been designed and tested to comply with all applicable FDA Recognized Standards. There are no device-specific guidance documents, special controls, and/or requirements in the device-specific classification regulation regarding performance data that are applicable to the subject device. All necessary performance testing has been conducted to support determination of substantial equivalence. Results confirm by examination and provision of objective evidence that the design output met the design input requirements in conformance with the following recognized consensus standards:

- ISO 14971 Third Edition 2019-12, Medical Devices – Application of Risk Management to Medical Devices.
- ANSI AAMI IEC 62304:2006, Medical device software - Software life cycle processes.
- ISO 15223-1 Third Edition 2016-11-01, Medical Devices – Symbols to be Used with Medical Device Labels, Labelling And Information to be Supplied –Part 1: General Requirements.

Electrical Safety and Electromagnetic Compatibility (EMC)

Electrical safety and EMC testing were conducted on the CardioSTAT® ECG Test Solution and conformance has been shown to the following standards:

- ANSI/AAMI ES60601-1:2005 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text), Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD).
- IEC 60601-1-2 Edition 4.0 2014-02, Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Disturbances – Requirements and Tests.
- IEC 60601-1-11 Edition 2.0 2015-01, 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.
- ANSI AAMI IEC 60601-2-47:2012/(R)2016, Medical electrical equipment -- Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems.

Biocompatibility

The biocompatibility evaluation for the CardioSTAT® ECG Test Solution was conducted in accordance with the FDA guidance Use of International Standard ISO 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process, Document issued on: September 4, 2020 and International Standard ISO 10993-1 “Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process,” as recognized by FDA. The battery of testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation

The CardioSTAT® ECG Recorder is considered a surface device for contact with intact skin for a duration likely to exceed 24 hours but not 30 days.

Animal

No Animal or clinical studies have been conducted in support of the CardioSTAT® ECG Test Solution.

Clinical

Clinical data in the form of literature is included as follows:

In support of CardioSTAT® ECG Test Solution arrythmia detection performance when applied horizontally as compared to a standard Holter recorder.

Nault I, André P, Plourde B, Leclerc F, Sarrazin JF, Philippon F, O'Hara G, Molin F, Steinberg C, Roy K, Blier L, Champagne J.

Validation of a novel single lead ambulatory ECG monitor - Cardiostat™ - Compared to a standard ECG Holter monitoring

J Electrocardiol. 2019 Mar-Apr;53:57-63. doi: 10.1016/j.jelectrocard.2018.12.011. Epub 2018 Dec 19.

In this paper, arrhythmia detection accuracy was compared between CardioSTAT® ECG Test Solution and a standard 24 h Holter ECG monitoring. Two hundred twelve patient recordings were compared. AF was diagnosed in 73 patients. Agreement between CardioSTAT® ECG Test Solution ECG and standard Holter monitoring was 99% for AF detection. Authors conclude that CardioSTAT® ECG Test Solution showed excellent correlation with the standard Holter ECG monitoring for AF detection. Added value of the CardioSTAT® ECG Test Solution includes longer monitoring duration, less cumbersome installation and water resistance.

In support of CardioSTAT® ECG Test Solution performance in the VSL (Vertical Sternal Lead) position and in support of its performance for a home application modality.

Benjamin H, Bischof M, Goldshtein D, Fecteau P, Newman D.

A pandemic response to home delivery for ambulatory ECG monitoring: Development and validation

J Electrocardiol. 2021 Jan-Feb;64:72-75. doi: 10.1016/j.jelectrocard.2020.11.003. Epub 2020 Nov 18.

In response to the COVID-19 pandemic, a protocol was designed for mail-out devices and educational materials created to teach patients how to install the CardioSTAT® ECG recorder for 2 weeks of continuous ambulatory ECG monitoring. We compared data collection from two sequential patient populations; one who received standard device application in the same clinic in the months before the pandemic response, and another, who received their device by mail for self-installation at home in the VSL position. Patients received a single phone call when the device was mailed and were able to contact the manufacturer as needed for support. A total of 47 devices were assessed from each group. Each group was similar in age (70 vs 65 years), and clinical indication for monitoring. Overall, it was found that a mail-delivered home-based recording platform can be reliably used to acquire clinical data with similar data quality and patient compliance as a conventional in-clinic model for long term ambulatory ECG monitoring.

In support of CardioSTAT® ECG Test Solution performance with regards to patient wear time in long-term (up to 14 days) ambulatory environments.

Yennikomshian M, Jarvis J, Patton C, Yee C, Mortimer R, Birnbaum H, Topash M. Cardiac arrhythmia detection outcomes among patients monitored with the Zio patch system: a systematic literature review

ISSN: 0300-7995 (Print) 1473-4877 (Online) Journal homepage: https://www.tandfonline.com/loi/icmo20

This meta-analysis reports on twenty-three publications (22 unique studies). The unweighted mean wear time of the Zio patch was 10.4 days (median ranging from 5 to 14 days). Findings from the review suggest that long-term, continuous, uninterrupted monitoring with Zio results in longer patient wear times and higher cardiac arrhythmia detection rates compared with outcomes reported in previous reviews of short-duration (24–48 h) cardiac rhythm recording studies.

Icentia Post Market data from Canada and UK is compared to the study above. When prescribed for 14 days, CardioSTAT® ECG Test Solution wear time in post-market data from Canada and UK (33486 ECG tests) was 13.1 days (standard deviation of 1day and median of 13.9 days). Based on the Zio patch literature review and CardioSTAT® post-market data, the CardioSTAT® ECG Test Solution wear time is shown to be equivalent to or longer than the Zio patch device.

5.8. CONCLUSION

The CardioSTAT® ECG Test Solution is substantially equivalent to the predicate and reference devices.