09/20/2024

Mezoo Co., Ltd.
Jessica Kim
Regulatory Affairs Manager
Room 808, 200 Gieopdosi-ro, Jijeong-myeon
Gangwon-do, Seoul 26354
Korea, South

Re: K232670
Trade/Device Name: HiCardi+ H100
Regulation Number: 21 CFR 870.2800
Regulation Name: Medical Magnetic Tape Recorder
Regulatory Class: Class II
Product Code: MLO, DQK
Dated: August 23, 2024
Received: August 23, 2024

Dear Jessica Kim:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Kimberly N. Crowley -S

For: Jennifer Kozen
Assistant Director
DHT2A: Division of Cardiac
Electrophysiology, Diagnostics, and
Monitoring Devices
OHT2: 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)*
K232670

Device Name
HiCardi+ H100

Indications for Use *(Describe)*
The HiCardi+ H100 is intended to record symptomatic and asymptomatic cardiac events and continuous electrocardiogram (ECG) for 72 hours from ambulatory patients by attaching HiCardi+ H100 SmartPatch to the skin surface. ECG records are stored in SmartPatch for review by the clinician after the recording period (up to 72 hours) is completed. It is indicated for use on 22 years or older who may be symptomatic and/or asymptomatic or suffer from transient symptoms as palpitations, shortness of breath, dizziness, light-headedness, fatigue, or anxiety. The reported ECG metrics include preliminary indications of the irregular beat and/or rhythm and heart rate measurement based on a single-lead ECG basis. The arrhythmia information addressed in the report does not contain diagnostic interpretation; the reported indication is provided for review by the intended user to make 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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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

SUBMITTER

Applicant:

MEZOO CO., LTD.
#808, Medical Device Complex Center,
200 Gieopdosi-ro, Jijeong-myeon,
Wonju-si, Gangwon-do, 26354
Republic of Korea

Phone number: +82-33-761-2006
Fax number: +82-33-761-2036

Official Correspondent:

Boram Kim
RA manager of MEZOO
brkim@me-zoo.com
#808, Medical Device Complex Center,
200 Gieopdosi-ro, Jijeong-myeon,
Wonju-si, Gangwon-do, 26354
Republic of Korea

Date Prepared: August 30, 2023

DEVICE

Trade Name (Proprietary Name)	HiCardi+ H100
Common Name	Wearable ECG ambulatory recorder
Classification Regulation	870.2800: Recorder, Magnetic Tape, Medical 870.1425: Computer, Diagnostic, Programmable
Device Class	Class II
Product Code	MLO, DQK

PREDICATE DEVICE (Legally Marketed Device)

Trade Name	ZIO® SkyRunner (SR) Electrocardiogram (ECG) Monitoring Service
510(k) Submitter/Holder	iRhythm Technologies, Inc.
510(k) Number	K143513

DEVICE DESCRIPTION

The HiCardi+ H100 consists of two components:

- Patient-worn ECG patch (Sensor, SmartPatch);
- Review & Report Generation Software (LiveStudio).

The **SmartPatch** is a wearable and reusable patch device intended to measure ECG signals from a patient for 72 hours. The SmartPatch is intended to record ECG signals and automatically indicate the irregular beat and/or rhythm of the recorded ECG data to aid the clinician in finalizing the ECG interpretation. The SmartPatch has an Event Button the patient can press to record symptoms, such as heart palpitations, dizziness, or chest pain, etc.

The **LiveStudio** is a review software operating on a personal computer (PC). The software visualizes the ECG data and preliminary indications from the SmartPatch for review, editing, and interpretation by the clinician. The LiveStudio provides tools to assist the clinician with their review. The final report includes the summary results of the review and can be documented by PDF formatted documents and printed by a printer connected to the PC.

INDICATIONS FOR USE

The HiCardi+ H100 is intended to record symptomatic and asymptomatic cardiac events and continuous electrocardiogram (ECG) for 72 hours from ambulatory patients by attaching HiCardi+ H100 SmartPatch to the skin surface. ECG records are stored in SmartPatch for review by the clinician after the recording period (up to 72 hours) is completed. It is indicated for use on 22 years or older who may be symptomatic and/or asymptomatic or suffer from transient symptoms as palpitations, shortness of breath, dizziness, light-headedness, fatigue, or anxiety. The reported ECG metrics include preliminary indications of the irregular beat and/or rhythm and heart rate measurement based on a single-lead ECG basis. The arrhythmia information addressed in the report does not contain diagnostic interpretation; the reported indication is provided for review by the intended user to make a diagnosis based on clinical judgment and experience.

Contraindications

- The HiCardi+ H100 is contraindicated for patients with known allergies or hypersensitivity to medical-grade adhesives gel or hydrogel.
- The HiCardi+ H100 is contraindicated for patients with potentially life-threatening arrhythmias, or who require inpatient monitoring or immediate analysis of their ECG.
- The HiCardi+ H100 is contraindicated for a handicapped person who cannot carry a patch-type electrocardiograph.
- The HiCardi+ H100 is contraindicated for a person who shows a skin disease or functional disorder when the patch-type electrocardiograph comes into contact with it.
- The HiCardi+ H100 is contraindicated for subjects who cannot read the consent form (illiterate, foreigners, etc.).

Substantial Equivalence Discussion

The Device Comparison Table in Section 11. Executive Summary/Predicate Comparison and the discussion of similarities and differences in Section 12. Substantial Equivalence Discussion show that the indications for use, technology, and performance of (MEZOO CO., LTD., HiCardi+ H100) are substantially equivalent with the predicate devices (iRhythm Technologies, Inc., ZIO® SkyRunner (SR) Electrocardiogram (ECG) Monitoring Service).

Characteristics	Subject Device	Predicate Device
ECG Recording Characteristics		
ECG Channel	1 channel	1 channel
ECG Lead Vector	Modified Lead II recorder and Modified Lead II analysis	Modified Lead II recorder and Modified Lead II analysis
Recorder Power Supply	Rechargeable battery	Non-rechargeable battery
Recording Duration	Up to 3 days (The internal battery of the SmartPatch is continuously recharged when it is in the charger.)	Up to 14 days
Electrode Detachable	Detachable, Non-integrated into the device	Non-detachable, integrated into the device
Electrode Materials	Silver-Silver Chloride conventional electrodes/hydrogel, and skin adhesive	Silver-Silver Chloride conventional electrodes/hydrogel, and skin adhesive
Recorder User Interface	Two Buttons - Power On/Off Button for on/off control - Event Button for patient event marking	Single button for on/off control/ Patient event marking
Wear	body-worn	body-worn
Sterile	No	No
Recording Type	Continuous	Continuous
Data Transmission Characteristics		
Data Telemetry	No	Yes
Data Transfer / Analysis Software Interface	Wireless technology for data transfer is not applied. Software interface suitable for the host computer environment.	Bluetooth technology and cellular phone technology & software interface suitable for the host computer environment.
Performance Characteristics		
Performance Safety Standards Compliance	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-47 ISO 10993-1 ANSI/AAMI EC12 ANSI/AAMI EC57	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-47 ISO 10993-1 ANSI/AAMI EC12 ANSI/AAMI EC57
Documentation Level (or Software Level of Concern before 2023)	Enhanced Documentation	Moderate
Physician Report Output	Yes, printable, with analysis metrics for recorded ECG signal	Yes, printable, with analysis metrics for recorded ECG signal

PERFORMANCE DATA

Verification and validation activities established the safety and performance characteristics of the subject device with respect to the predicate. The following performance data were provided in support of the substantial equivalence determination.

Sterilization and Shelf-Life Testing

The HiCardi+ H100 and its standard accessories are not sterilized and do not have a shelf-life.

Biocompatibility Testing

ECG electrode

The biocompatibility assessment for ECG electrode was performed, included in-vitro cytotoxicity, irritation and sensitization according to the ISO 10993-1 standard. Please refer to Section 15. Biocompatibility in this submission for details.

Software Verification and Validation Testing

Software verification and validation activities were performed in accordance with IEC 62304 and FDA's guidance, General Principles of Software Validation, and documentation is provides as recommended by FDA's guidance, Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices and Content of Premarket Submissions for Management of Cybersecurity in Medical Devices. Please refer to Section 16. Software in this submission for details.

Electrical Safety and Electromagnetic Compatibility (EMC) Testing

The HiCardi+ H100 Wearable ECG ambulatory recorder substantially has been tested in accordance with the IEC 60601-1, IEC 60601-1-11, ISO 60601-2-47 standards for safety and the IEC 60601-1-2 standard for EMC. Please refer to Section 17. Electromagnetic Compatibility and Electrical Safety in this submission for details.

Bench Testing

Bench tests were conducted to verify that the subject device met all design specifications as was Substantially Equivalent (SE) to the predicate devices. The test results demonstrated that the proposed device complies with the following test report:

- General Safety (IEC 60601-1)
- Electromagnetic Compatibility (IEC 60601-1-2)
- Usability / Human factor (IEC 60601-1-6, IEC 62366-1)
- Home Healthcare (IEC 60601-1-11)
- Ambulatory ECG (IEC 60601-2-47)
- Li-ion Rechargeable Battery (IEC 62133-2)
- Protection against water and solid foreign objects (IEC 60529)
- Shock & Vibration Test Report (IEC 60068-2-27, 2-64)
- Temperature and Pressure for Operation and Storage (IEC 60068-2-13, 2-39)

- Packaging Performance (ISTA 3A)
- Biocompatibility (ISO 10993-1, -5, -10, -23)
- Disposable ECG electrodes Performance (ANSI/AAMI EC12)
- Software Verification and Validation (IEC 62304)
- Validation of heart rate detection and development of arrhythmia detection algorithm (IEC 60601-2-47, EC57)

Compliance to applicable standards includes IEC 60601-1, IEC 60601-1-2, IEC 60601-1-6, IEC 62366-1, IEC 60601-1-11, IEC 60601-2-47 (EC57), IEC 62133-2, IEC 60529, IEC 60068-2-27, IEC 60068-2-64, IEC 60068-2-13, IEC 60068-2-39, ISTA 3A, ISO 10993-1, -5, -10 -23, ANSI/AAMI EC12, IEC 62304 requirements.

The bench test report of this submission showed that substantial equivalence has demonstrated to be suitable for the subject device. Please refer to Section 18. Performance Testing – Bench in this submission for details.

Animal Study

Animal performance testing was not required for this device.

Clinical Study

Clinical data was reviewed to demonstrate the substantial equivalence of the subject device.

CONCLUSIONS

The comparison and performance data presented above support a determination of substantial equivalence of the MEZOO CO., LTD., HiCardi+ H100 to its predicate device, the iRhythm Technologies, Inc., ZIO® SkyRunner (SR) Electrocardiogram (ECG) Monitoring Service.

The minor differences between the current subject device (MEZOO CO., LTD., HiCardi+ H100) and the predicate devices (iRhythm Technologies, Inc., ZIO® SkyRunner (SR) Electrocardiogram (ECG) Monitoring Service) do not adversely affect the safety or effectiveness.

Therefore, it is concluded that the HiCardi+ H100 is substantially equivalent to the identified predicate devices.