November 21, 2023

Trismed Co., Ltd.
Sul Ki Lee
Senior Researcher
409 SMECA, 65 Techno 3-ro, Yuseong-gu
Daejeon, 34016
South Korea

Re: K230834
Trade/Device Name: CARDIPIA ECG / Model: CARDIPIA400H, CARDIPIA800H
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II
Product Code: DPS
Dated: October 18, 2023
Received: October 19, 2023

Dear Sul Ki Lee:

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.

510(k) Number *(if known)*
K230834

Device Name
CARDIPIA ECG (Model: CARDIPIA400H, CARDIPIA800H)

Indications for Use *(Describe)*
CARDIPIA800H and CARDIPIA400H are the portable recording device which is to acquire, display, record, and export 12-lead ECG signals and data defined as the electrical heart activity induced on patient skin. ECG are intended to use for adult and pediatric which is defined between 0 and 15 years old by a physician, trained or licensed professionals in a hospital, clinic, medical office, medical use facilities or a prescribed environment under the direction of a physician. CARDIPIA800H and CARDIPIA400H have the resting ECG,12/6-recording and displaying, 12-lead ECG measurement, and optional export ECG data for hospital information system.
NOTE: ECG should not be used as the patient monitoring system for long term patient monitor.

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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510(k) Summary

This 510(k) Summary is being submitted in accordance with the requirements of as required by section 807.92(c).

I. SUBMITTER

TRISMED CO., LTD.
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Tel: +82-42-936-7201
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Contact person: Sul Ki Lee
Date Prepared: March 23, 2023

II. DEVICE

Device Name: CARDIPIA400H, CARDIPIA800H
Trade Name: CARDIPIA ECG
Common Name: Electrocardiograph
Regulatory Class: II
Product Code: DPS
Regulatory Description: Electrocardiograph (21 CFR 870.2340)

III. PREDICATE DEVICE

The CARDIPIA ECG (CARDIPIA400H, CARDIPIA800H) addressed in this premarket notification, is substantially equivalent to the following commercially available electrocardiograph device:

Predicate device (Legally Marketed Device)

• K133622 – MAC2000 ECG Analysis System, WIPRO GE Healthcare

IV. DEVICE DESCRIPTION

The CARDIPIA800H and CARDIPIA400H consist of main body, power cable. Both devices are intended to be used with 3rd party lead electrodes supplied to a patient by a physician or a monitoring center. High quality FDA cleared lead electrodes should be used.

TRISMED's CARDIPIA ECG (model: CARDIPIA800H, CARDIPIA400H) feature the resting ECG, 12/6-recording and displaying, 12-lead ECG measurement, and optional export ECG data for hospital information system. CARDIPIA ECG is able to record the standard 12-lead resting ECG with 12, 6 or 3 channel format and any lead combinations of the 12 leads in automatic or manual mode. The preview mode allows to verify the content of the report on the display before printing it. This is useful to avoid printing reports with artifacts or unusable signal. CARDIPIA ECG is freely operated by main AC power without additional adjustment, or by the built-in rechargeable battery which can be used for a limited time in place of AC power. CARDIPIA ECG can save internal memory and export all patient data from USB memory stick or import from USB memory stick to on data management mode.

V. INDICATIONS FOR USE

CARDIPIA800H and CARDIPIA400H are the portable recording device which is to acquire, display, record, and export 12-lead ECG signals and data defined as the electrical heart activity induced on patient skin. ECG are intended to use for adult and pediatric which is defined between 0 and 15 years old by a physician, trained or licensed professionals in a hospital, clinic, medical office, medical use facilities or a prescribed environment under the direction of a physician. CARDIPIA800H and CARDIPIA400H have the resting ECG,12/6-recording and displaying, 12-lead ECG measurement, and optional export ECG data for hospital information system. NOTE: ECG should not be used as the patient monitoring system for long term patient monitor.

VI. SUBSTANTIAL EQUIVALENCE TABLE

The submission provides a comparison between the new device, the CARDIPIA ECG (Type: CARDIPIA800H , CARDIPIA400H), compared to the MAC2000 ECG Analysis System by WIPRO GE Healthcare cleared under K133622. The following is a comparison table which includes a comparison of the indications for use, technological characteristics, principles of operation, and performance specifications. There are no fundamental technological differences between CARDIPIA ECG and predicate MAC2000 regarding the basis for the determination of substantial equivalence. It has no effect on the safety or efficacy of the subject device and does not raise any potential safety risks, and the subject device is identical in performance to the legally marketed device.

Characteristics	Subject Device – CARDIPIA ECG (CARDIPIA400H, CARDIPIA800H)	Predicate Device - MAC2000 ECG Analysis System
Indication for Use	CARDIPIA800H and CARDIPIA400H are the portable recording device which is to acquire, display, record, and export 12-lead ECG signals and data defined as the electrical heart activity induced on patient skin. ECG are intended to use for adult and pediatric which is defined between 0 and 15 years old by a physician, trained or licensed professionals in a hospital, clinic, medical office, medical use facilities or a prescribed environment under the direction of a physician. CARDIPIA800H and CARDIPIA400H have the resting ECG,12/6-recording and displaying, 12-lead ECG measurement, and optional export ECG data for hospital information system. NOTE: ECG should not be used as the patient monitoring system for long term patient monitor.	The MAC™2000 ECG Analysis System is a portable device intended to be used by or under the direct supervision of a licensed healthcare practitioner using surface electrodes to acquire, analyze, display, and record information for adult and pediatric populations in a hospital, medical professional's facility, clinics, physician's office or outreach centers. NOTE: Pediatric populations are defined as patients between the ages of 0 and 15 years. The MAC™2000 ECG Analysis System provides the following modes of operation: • Resting ECG mode • Arrhythmia mode • Exercise mode for exercise stress testing (optional) • RR analysis mode for RR interval analysis (optional)

		The basic system prints 6 or 12 leads of ECG and is upgradeable to provide software options such as 12-lead ECG measurement and interpretive analysis. Arrhythmia detection is provided for the convenience of automatic documentation. Transmission and reception of ECG data to and from a central ECG cardiovascular information system is optional.
Product Code	DPS	DPS, DQK, DXH
Operating Principle	Electrocardiographs	Electrocardiographs (DPS)
Target Population	Pediatric patient (0 ~ 15 years) and adult	Pediatric patients (0~15 years) and adult
ECG Acquisition	12-lead ECG with simultaneous 10-lead	12-lead simultaneous acquisition
Lead	12 Standard Leads : I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6	12-lead analysis
Safety	EN 60601-1 (IEC 60601-1) Medical electrical equipment – Part 1: General Requirements for Safety Class I (Degree of protection against electrical shock) Defibrillation proof (5000VDC) based on type CF applied part Complied IEC60601-1	EN 60601-1 (IEC 60601-1) Medical electrical equipment – Part 1: General Requirements for Safety IEC60601–1 protection class I Type CF defibrillation-proof applied part
EMC	IEC 60601-1-2 General Requirements for Safety Electromagnetic Compatibility CISPR 11, Class A / IEC60601-1-2	CISPR11, Group 1, Class B
Performance	IEC 60601-2-25 Safety of Electrocardiographs	IEC 60601-2-25 Safety of Electrocardiographs
Sensitivity	1.25, 2.5, 5, 10, 20, 40mm/mV, Auto	2.5, 5, 10, 20, 40 mm/mV with ±5% accuracy
Recording Speed	5, 10, 12.5, 25, 50, 100 mm/s	5, 12.5, 25, and 50 mm/s

QRS Beat Display & Sound	30 ~ 240 bpm on real time.	Heart Rate meter: 30 to 300 BPM QRS Detection: available
Sampling Rate	1000 samples/sec/channel	500 or 1000 samples/second/channel
Filters	Muscle Filter: 25 / 35 Hz Drift filter(baseline): 0.1/ 0.15 / 0.25/ 0.32 / 0.5 Hz AC filter : 50 / 60 Hz High frequency filter: 75 / 100 / 150 / 200 Hz	Muscle: 20 Hz, 40 Hz, 100 Hz, 150 Hz Automatic Baseline correction: User-selectable Hight cutoff Frequency: configurable at 20 Hz, 40 Hz, 100 Hz, 150 Hz
Display Type	Color TFT 7” LCD (Viewing area: 154.08mm x 85.92mm), Dots: 800 x 480	7–inch (177.8 mm) color TFT graphics display with support of minimum 32K colors Resolution WVGA – 800 x 480 pixels
Patient Data	Patient Name, ID, Code(barcode), Sex, Ethnic, Birthday, Age, Weight, Height, Drugs, Smoker, Systolic, Diastolic, Physician, hospital name	Patient information entry: Patient ID, Secondary Patient ID, Height, Weight, Gender, Race, Pacemaker Patient, Systolic BP, Diastolic BP, Location#, Room, Order Number, Phone Number, Medication, Ordering Physician, Referring Physician, Attending Physician, Technician, Test indication, four user-definable fields.
Key Operation	Alphanumeric key by membrane and LCD touch screen	Membrane keyboard with tactile feedback – Soft function keys, alphanumeric keys (Qwerty key set),
Weight	CARDIPIA 400H : 2.8 Kg with battery CARDIPIA 800H : 3.5 Kg with battery	approx. 5 kg (11.0 lb) (including battery, without paper)
Dimensions	CARDIPIA400H : 313 (L) x 252 (W) x 107 (H) CARDIPIA800H : 332 (L) x 308 (W) x 107 (H)	390 x 330 x 200 mm Width x Depth x Height
Operation Power	100 - 240VAC ±10 % 50/60 Hz free voltage	100 to 240 VAC ±10%
Input Impedance	Greater than 100 MΩ per 10 Hz	>10MΩ @ 10 Hz

Leakage Current	Less than 10μA	<10μA (Normal Condition)
Lead Detection	Lead-off detection for individual 10-lead.	All disconnected lead detection except RL and RA
Battery	Built-in rechargeable battery. CARDIPIA400H: NiMH 19.2V 1,000mA 90reports (90min) per 6-ch x 1 (5sec) auto record with fully charged battery CARDIPIA800H: NiMH 19.2V 2,200mA 170reports (170 min) per 12-ch x 1 (5sec) auto record with fully charged battery	Replaceable and rechargeable, Lithium Ion 14.4V, 2.2 AH ±10% 100 single page resting ECG recording or 3 hours (typical) of continuous monitoring without printing (minimum) Approximately 3.5 hours after low battery shut down (with device off) to 90% full capacity
Sterilization	Not Applicable	Not Applicable
Printer	Thermal printer head (8 dots/mm) / 203 (vertical) x 508 (horizontal) dpi	Integrated thermal dot array 8 dots/mm
Data Transfer I/F	USB memory stick / USB port / Ethernet LAN	RS232 Serial Cable / RJ45 Wired LAN / Wireless LAN /
Data Storage	Internal memory: Standard 10,000 records / Optional external USB memory stick (10,000 records per 1GB)	Internal storage of 100 or 200 ECGs
Pace Maker Detection	Option	available

VII. PERFORMANCE DATA

Non-Clinical Performance Data:

Non-clinical performance testing has been performed on CARDIPIA ECG, the subject device, and demonstrates compliance with the following International and FDA-recognized consensus standards and FDA guidance document.

- IEC 60601-1: 2005+A1:2012 +A2:2020 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2014+A1:2020 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC 60601-2-25:2011 Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs
- IEC 62366-1:2015, AMD1:2020 Medical devices — Part 1: Application of usability engineering to medical devices

- IEC 62304:2006 +AMD1:2015 Medical device software - Software life-cycle processes
- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices issued May 11, 2005.
- Content of Premarket Submissions for Management of Cybersecurity in Medical Devices Guidance for Industry and Food and Drug Administration Staff Document Issued on: October 2, 2014.

The subject device was tested in accordance with the internal Verification and Validation processes of TRISMED CO., LTD. Verification and Validation tests have been performed to address intended use, the technological characteristics claims, requirement specifications, and the risk management results.

The test results in this 510(k), demonstrate those CARDIPIA ECG:

- comply with the aforementioned international and FDA-recognized consensus standards and
- FDA guidance document, and
- meets the acceptance criteria and is adequate for its intended use.

Therefore, CARDIPIA ECG is substantially equivalent to the currently marketed predicate devices, in terms of safety and effectiveness.

Clinical Testing:

CARDIPIA ECG does not require clinical studies to demonstrate substantial equivalence to the predicate devices.

VIII CONCLUSIONS

Verification and Validation activities required to establish the safety and effectiveness of CARDIPIA ECG were performed. Testing involved system-level tests, performance tests, and safety tests from risk analysis. These tests demonstrated the subject devices meet pre-defined functionality requirements.

The subject device and predicate device are substantially equivalent in the areas of technical characteristics, general function, application, and intended use. Test results with the substantial datasets demonstrate that the subject device is as safe and effective as the predicate device. Therefore, the subject device is substantially equivalent to the predicate device.