December 5, 2025

Huinno Co., Ltd.
% Edward Park
Official Correspondent for HUINNO Co., Ltd.
Lighten Bridge, LLC
4408 Tortuga Ln
McKinney, Texas 75070

Re: K243438
Trade/Device Name: MEMO Patch M (MPT-E08R-UNC01)
Regulation Number: 21 CFR 870.2920
Regulation Name: Telephone Electrocardiograph Transmitter And Receiver
Regulatory Class: Class II
Product Code: DXH
Dated: November 5, 2025
Received: November 5, 2025

Dear Edward Park:

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,

JENNIFER W. SHIH -S

Jennifer 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K243438

Device Name
MEMO Patch M (MPT-E08R-UNC01)

Indications for Use *(Describe)*
The MEMO Patch M is intended to record, transfer and store single-channel electrocardiogram via USB transmission to PC. 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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510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR §807.92.

1. Applicant Information

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2. Correspondent, US Agent

Official Correspondent:	Edward Park
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Phone:	+1-972-800-0044
Email:	lightenbridge@gmail.com

3. Date Prepared November 10, 2024

4. Device Information

Proprietary/Device/ Trade Name:	MEMO Patch M
Common Name:	Ambulatory ECG Monitor
Classification Name:	Transmitters and receivers, electrocardiograph, telephone
Product Code:	DXH
Classification Panel:	Cardiovascular
Device Class:	II

5. Predicate Information

V-Patch Cardiac Monitor (Shandong CoreCare Technology Limited, K222842, 10/20/2022)

- Common Name: Ambulatory Electrocardiogram (ECG) Recorder

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- Regulation Name: Telephone electrocardiograph transmitter and receiver
- Regulation Number: 21CFR§870.2920
- Device Class: II
- Product Code: DXH
- Classification Panel: Cardiovascular

6. Device Description

The MEMO Patch M is a continuous electrocardiogram (ECG) recording device to record, store, and transfer single channel ECGs and is designed for a fully retrospective review of data that was recorded over the specified wear period. The MEMO Patch M has Bluetooth module to verify ECG signals with mobile device and to authenticate the activation of MEMO Patch M. The device is in the form of an ECG patch that records ECG signals. As well the patch connects with a cradle and transmits ECG data via USB communication to PC. Healthcare professional actives the ECG patch, connects the patch with the cradle to the PC, and accesses raw ECG data on the ECG dataloader viewer. The MEMO Patch M includes a battery powered electronic unit that is used with off-the-shelf (OTS) disposable medical grade gel electrodes for long term monitoring. The adhesive electrodes should be replaced by the user every 24 hours or when it no longer adheres to skin. The device is only intended for manual interpretation, and does not provide any automated ECG analysis. The intended clinical use of the ECG is to display the waveforms of the P, QRS, and T waves of the measured electrocardiogram. The intended clinical use of the ECG waveform to be limited to the discrimination of normal sinus rhythm from easily identifiable, non-lethal arrhythmias. The device is not intended for additional analysis or the detection of specific cardiac conditions, such as ischemia, myocardial infarction, and ldft ventricular hypertrophy, etc. The Ambulatory ECG Monitor is intended to capture and continuous electrocardiogram information for long-term monitoring. The device records continuously for the entire wear period, up to 8 days. The MEMO Patch M is a prescription use device and the recorded ECG data is intended to be used with patient-triggered events. When a patient presses the event marking button during a symptom, this event is recorded and displayed on the PDF report of raw ECG data. However, there is no ability to detect specific cardiac events on the PDF report.

7. Indications for Use

The MEMO Patch M is intended to record, transfer and store single-channel electrocardiogram via USB transmission to PC. 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 for pediatric use.

8. Substantial Equivalence

The MEMO Patch M substantially equivalent to its legally marketed predicate device, V-Patch™ Cardiac Monitor, K222842 (Shandong CoreCare Technology Limited). The subject MEMO

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Patch M is identical in form and function to the predicate device such as population, location attaching patch, OTS electrode, device features, communication type, replaceable battery, and software level. The two devices have identical intended use, physical characteristics, and technological characteristics.

9. Comparison of Technological Characteristics with the predicate Device [807.92(a)(6)]

Feature	MEMO Patch M K243438 (Subject Device)	V-Patch Cardiac Monitor K222842 (Predicate Device)
Indications for use	Ambulatory, long-term, continuous ECG monitoring	Same
Product Code	DXH, Telephone Same electrocardiograph transmitter and receiver	Same
Regulation	21 CFR§870.2920	Same
Classification	II	Same
Indications for Use	The MEMO Patch M is intended to record, transfer and store single-channel electrocardiogram via USB transmission to PC. 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 V-Patch Cardiac Monitor is intended to record, transfer and store single-channel 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 for pediatric use.
Indicated Use Method	Apply patch on upper left chest	Same
Intended Use	Ambulatory, Long-term, Continuous ECG monitoring	Same
Type of use	Rx only	Same
Alarms, arrhythmia	No	Same
Population	Adult	Same

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Anatomical Sites	Chest	Same
Electrodes	Attachable standard ambulatory OTS electrodes with conductive gel.	Same
Single Use/Reusable	Electronic unit is reusable. OTS electrodes are single use.	Same
ECG and Events Storage	-ECG data and event records are saved in the internal memory of the patch device -The patch device transfers the data to the PC for healthcare professionals.	-Event records are saved in the internal memory of the patch device (Vpod) -Vpod device transfers ECG data to the Bluetooth enabled device (Vcell) which is connected to the internet.
Real time ECG View	No	Same
Sampling Rate	250 Hz	Same
Activation	Activation through mobile app after attaching the patch	-Automatic turn on upon skin contact -Mobile app
Transmission method	USB, Class II Bluetooth	Class II Bluetooth
Power Supply	Replaceable battery	Same
Software Level of Concern	Moderate	Same

10. Performance Data [807.92(b)]

All necessary testing was conducted on MEMO Patch M to support a determination of substantial equivalence to the predicate device.

11. Nonclincial Testing Summary [807.92(b)(1)]

The MEMO Patch M was successfully passed its nonclinical testing. The testing activities included:

- Biocompatibility evaluation per ISO 10993-1:2018 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.
- Electromagnetic Compatibility per 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.
- Electrical Safety per IEC 60601-1:2005+A1:2012+A2:2020, Medical Electrical Equipment - Part 1: General requirements for basic safety and essential performance
- Ambulatory ECG testing per IEC 60601-2-47:2015, Medical electrical equipment - Part 2-47: Requirements for the safety, including essential performance, of ambulatory

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electrocardiographic systems

- Software verification and validation testing

12. Clinical Testing Summary {807.92(b)(2)1

No clinical testing is required to demonstrate substantial equivalence to the predicate V-Patch Cardiac Monitor (K222842).

13. Conclusion [807.92(b)(3)]

The MEMO Patch M has a same intended use, physical characteristics, and technological characteristics as the predicate. The minor difference between the devices do not raise different questions of safety or effectiveness. Therefore, the MEMO Patch M is substantially equivalent to its predicate device, the V-Patch Cardiac Monitor (K222842).