June 25, 2026

Seers Technology Co., Ltd.
% Diane Horwitz
Regulatory Consultant
Cardiovascular Biometrics Sourcing, LLC
6703 West 131st St.
Overland Park, Kansas 66209

Re: K253384
Trade/Device Name: mobiCARE Cardiac Monitoring System (mobiCARE-MC200M, mobiCARE-MC200ML, mobiCARE-MC200M7, mobiCARE-MC200ML7)
Regulation Number: 21 CFR 870.2800
Regulation Name: Electrocardiograph, Ambulatory (Without Analysis)
Regulatory Class: Class II
Product Code: MWJ
Dated: May 24, 2026
Received: May 26, 2026

Dear Diane Horwitz:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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)*
K253384

Device Name
mobiCARE Cardiac Monitoring System (mobiCARE-MC200M, mobiCARE-MC200ML, mobiCARE-MC200M7, mobiCARE-MC200ML7)

Indications for Use *(Describe)*
mobiCARE Cardiac Monitoring System is a wearable, ambulatory ECG recorder. It is indicated for use on patients who may be asymptomatic or who may suffer from transient symptoms such as palpitations, shortness of breath, dizziness, light headedness, pre-syncope, syncope, fatigue, chest pain and/or anxiety. mobiCARE Cardiac Monitoring System is intended for use by patients 18 years or older. The device is not intended for use with critical care patients or for real-time monitoring.

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 OF SAFETY AND EFFECTIVENESS

1. GENERAL INFORMATION

1.1 Submitter and 510(k) Owner

SEERS Co., Ltd.
(17707) 291-13, Dongbu-daero, Jinwi-myeon,
Pyeongtaek-si, Gyeonggi-do, Republic of Korea

1.2 Official Correspondent

Diane Horwitz, Ph.D.
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Phone (703) 307-2921
E-mail: dmh@mandellhorwitzconsulting.com

1.3 Date of Preparation

June 25, 2026

2. NAME OF THE DEVICE

2.1.1 Trade/Proprietary Name

mobiCARE Cardiac Monitoring System (mobiCARE-MC200M series)
Models: mobiCARE-MC200M, mobiCARE-MC200ML, mobiCARE-MC200M7, mobiCARE-MC200ML7

2.1.2 Classification Information

Classification Name:	Electrocardiograph, Ambulatory (Without Analysis)
Classification Regulation:	21 CFR 870.2800
Class:	II
Product Code:	MWJ
Panel:	Cardiovascular

3. PREDICATE DEVICE

The predicate device is the S-Patch Ex Wearable ECG Patch, Wellysis Corp, K231289

4. DESCRIPTION OF THE DEVICE

mobiCARE-MC200M/mobiCARE-MC200ML/mobiCARE-MC200M7/mobiCARE-MC200ML7 (“mobiCARE-MC200M series”) is single-channel, wearable, mobile and reusable ambulatory ECG recorder. It can continuously acquire and store the ECG signals through disposable electrodes for up to 6 or 9 days (expected continuous measurement time is different by the model). The mobiCARE-MC200M series is not intended for real-time monitoring.

ECG measurement is activated after generating the measurement code using the mobiCARE Cardio Hospital mobile phone application. Status for the patch connection, battery level and patch signal is confirmed using this mobile application.

The home user then wears the mobiCARE-MC200M device for the prescribed period of time, usually 6 days or 9 days (depending on the model). After the measurement is completed, recorded ECG signal can be uploaded to a compatible ECG viewing (and/or analyzing) platform by qualified clinicians using the mobiCARE Cradle and mobiCARE Cardio UPLoader.

The mobiCARE-MC200M series is a prescription device intended to be used with direction from Healthcare Professionals in accordance with the user manual.

5. INDICATIONS FOR USE

mobiCARE Cardiac Monitoring System is a wearable, ambulatory ECG recorder. It is indicated for use on patients who may be asymptomatic or who may suffer from transient symptoms such as palpitations, shortness of breath, dizziness, light headedness, pre-syncope, syncope, fatigue, chest pain and/or anxiety. mobiCARE Cardiac Monitoring System is intended for use by patients 18 years or older. The device is not intended for use with critical care patients or for real-time monitoring.

6. INDICATIONS FOR USE COMPARED TO THE PREDICATE

The intended use and indications for use of the subject and predicate are the same with the exception of the product name.

7. TECHNOLOGY CHARACTERISTICS COMPARED TO THE PREDICATE

The mobiCARE-MC200M series devices are similar in most characteristics to the predicate device. The slight technological differences (i.e., uploading of data and battery size) do not raise new issues of safety or effectiveness, as the subject device has been demonstrated to meet product requirements and specifications.

	mobiCARE Cardiac Monitoring System (mobiCARE-MC200M series) **Subject Device**	**S-Patch Ex Wearable ECG Patch K231289** **Predicate Device**
Product Code Regulation Review Panel	MWJ 21 CFR 870.2800 Cardiovascular	DSH 21 CFR 870.2800 Cardiovascular
Intended Use / Indications for Use Statement	mobiCARE Cardiac Monitoring System is a wearable, ambulatory ECG recorder. It is indicated for use on patients who may be asymptomatic or who may suffer from transient symptoms such as palpitations, shortness of breath, dizziness, light headedness, pre-syncope, syncope, fatigue, chest pain and/or anxiety. mobiCARE Cardiac Monitoring System is intended for use by patients 18 years or older. The device is not intended for use	S-Patch Ex wearable ECG patch is indicated for use on patients who may be asymptomatic or who may suffer from transient symptoms such as palpitations, shortness of breath, dizziness, light headedness, pre-syncope, syncope, fatigue, chest pain and/or anxiety. S-Patch Ex wearable ECG patch is intended for use by patients 18 years or older.

	mobiCARE Cardiac Monitoring System (mobiCARE-MC200M series) Subject Device	S-Patch Ex Wearable ECG Patch K231289 Predicate Device
	with critical care patients or for real-time monitoring.	
Monitoring duration	Up to 9 days, depending on model	100 hours (4.2 days)
Multiple patient use	Yes; device is disinfected between users	Yes; device is disinfected between users
ECG Dynamic Range	±10 % (± 5mV); complies with IEC 60601-2-47 standard	±10 mV
Applied Part Category	Type CF (cardiac floating)	Type CF (cardiac floating)
Data Storage and Transfer	mobiCARE Cardio UPLoader software on Healthcare Professional PC	Mobile gateway on home user's phone described in Instructions for Use.
Viewing Software Platform	3rd Party ECG Viewing Software	3rd Party ECG Viewing Software
Communication Protocol	- Main Body: Bluetooth Low Energy (2402 to 2480 MHz) - Cradle: USB 2.0	Bluetooth Low Energy (2402 – 2480 MHz)
Data Encryption	Advanced Encryption Standard-CCM mode	Advanced Encryption Standard-CCM mode

8. PERFORMANCE TESTING

Bench performance testing, a clinical performance test, human factors engineering testing, biocompatibility and disinfection and transportation validation support the conclusion that any differences between the mobiCARE-M200M series and the predicate device do not impact safety or effectiveness.

Performance tests included:

- Software verification and validation testing in compliance with ANSI AAMI IEC 62304:2006/A1:2016.
- Cybersecurity testing in compliance with FDA Guidance, Cybersecurity in Medical Devices, 2026.
- Biocompatibility testing of patient-contacting cable in compliance with ISO 10993-1 Sixth edition 2025-11.
- Transportation testing
- Expected service life evaluation
- Human factors validation testing in compliance with ANSI AAMI IEC 62366-1:2015+AMD1:2020.
- Electromagnetic compatibility and electrical safety testing in compliance with IEC 60601-1 Edition 3.2 2020-08, ANSI AAMI IEC 60601-1-2:2014, IEC 60601-1-6 Edition 3.2 2020-07, IEC 60601-1-11 Edition 2.1 2020-07, ANSI AAMI IEC 60601-2-47:2012/(R)2016.
- Compliance with defibrillation-proof requirements.
- Disinfection validation Reprocessing Medical Devices in Health Care Settings, 2015.
- Clinical performance test of electrode placement in compliance with ISO 14155 Third edition 2020-07.

9. CONCLUSIONS

The bench and clinical performance testing including software verification and validation, cybersecurity testing, biocompatibility, transportation, disinfection validation testing, and human factors validation testing provide evidence to support the conclusion that the mobiCARE MC200M device is substantially equivalent to the predicate device.