October 20, 2022

Shandong CoreCare Technology Limited
% Prabhu Raghavan
Principal Consultant
Mdqr, LLC.
1790 Montemar Way
San Jose, California 95125

Re: K222842
Trade/Device Name: V-Patch™ Cardiac Monitor
Regulation Number: 21 CFR 870.2920
Regulation Name: Telephone Electrocardiograph Transmitter And Receiver
Regulatory Class: Class II
Product Code: DXH
Dated: September 20, 2022
Received: September 20, 2022

Dear Prabhu Raghavan:

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

Jennifer Shih
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)*

K222842

Device Name

V-Patch™ Cardiac Monitor

Indications for Use *(Describe)*

The V-Patch Cardiac Monitor is intended to record, transfer and 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 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.

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510(k) Summary for K222842

Prepared in accordance with the requirements of 21 CFR 807.92

Submitter Information [807.92(a)(1)]

Sponsor/Applicant	Cao Cheng Chief Executive Officer Shandong CoreCare Technology Limited Suite 801-2, Incubator Phase I, Innovation Valley Jinan High-Tech Industrial Development Zone, Jinan, Shandong, China Phone: +86-18610294350 Email: cao.cheng@ecordum.cn
Submission Correspondent	Prabhu Raghavan Principal Consultant, MDQR, LLC Phone: 408-316-5707 Email: prabhu@mdqr.solutions
Secondary Correspondent, US Agent and Partner to Sponsor	Darin Slack Chief Executive Officer Versa Cardio, Inc. 255 E. Rincon, Suite 210 Corona, CA 92879 Phone: 855-329-5794 Email: darin@versacardio.com
Date Prepared	September 19, 2022

Device Information [807.92(a)(2)]

Trade Name	V-Patch™ Cardiac Monitor
Common Name	Transmitters and receivers, electrocardiograph, telephone
Classification	21 CFR§870.2920
Device Class	II
Product Code	DXH
Classification Panel	Cardiovascular

Predicate Information [807.92(a)(3)]

Predicate(s)	K193296, eCordum™ Cardiac Monitor, eCordum Inc.

Device Description [807.92(a)(4)]

The V-Patch Cardiac Monitor ("V-Patch CM") is a continuous electrocardiogram (ECG) recording device to record, store, and transfer single channel ECGs and is designed for remote ECG data collection and remote monitoring. The device is in the form of an ECG patch that records ECG signals and transmits directly to a Bluetooth™ enabled device. The V-Patch CM

has Bluetooth module for transferring ECG data from V-Patch CM to a Bluetooth enabled computing or mobile devices to be accessible to healthcare professionals.

The V-Patch CM 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 V-Patch CM is a prescription use device and the recorded ECG data is intended to be used with other patient data. The device does not provide any automated ECG analysis.

Indications for use [807.92(a)(5)]
The V-Patch Cardiac Monitor is intended to record, transfer and 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 intended for pediatric use.

Substantial Equivalence
The V-Patch CM substantially equivalent to its legally marketed predicate device, eCordum Cardiac Monitor, K193296 (eCordum Inc). The subject V-Patch CM is identical in form and function to the predicate device, using the same components, materials, and software as the predicate and is manufactured by Shandong CoreCare Technology Limited using the same manufacturing process. The two devices have identical intended use, physical characteristics, and technological characteristics.

Comparison of Technological Characteristics with the Predicate Device [807.92(a)(6)]

Feature	**V-Patch Cardiac Monitor (K222842) (Subject Device)**	**eCordum Cardiac Monitor (K193296) (Predicate Device)**
Intended Use	Ambulatory, long-term, continuous ECG monitoring	Same
Product Code	DXH, Telephone electrocardiograph transmitter and receiver	Same
Regulation	21 CFR§870.2920	Same
Classification	II	Same

Comparison of Technological Characteristics with the Predicate Device [807.92(a)(6)]

Feature	V-Patch Cardiac Monitor (K222842) (Subject Device)	eCordum Cardiac Monitor (K193296) (Predicate Device)
Indications for Use	The V-Patch Cardiac Monitor is intended to record, transfer and 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 intended for pediatric use.	The eCordum Cardiac Monitor is intended to record, transfer and 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 intended for pediatric use.
Indicated Use Method	Apply patch on upper left chest	Same
Type of use	Rx only	Same
Alarms, arrhythmia detection	No	Same
Population	Adult	Same
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	Transmit ECG data to a Bluetooth enabled device.	Same
Real time ECG View	No	Same
Sampling Rate	250 Hz	Same
Activation	Automatic turn on upon skin contact Mobile app	Same

Comparison of Technological Characteristics with the Predicate Device [807.92(a)(6)]

Feature	V-Patch Cardiac Monitor (K222842) (Subject Device)	eCordum Cardiac Monitor (K193296) (Predicate Device)
Transmission method	Class II Bluetooth	Same
Power Supply	Replaceable battery	Same
Software Level of Concern	Moderate	Same

Performance Data [807.92(b)]

All necessary testing was conducted on V-Patch Cardiac Monitor to support a determination of substantial equivalence to the predicate device.

Nonclinical Testing Summary [807.92(b)(1)]

The V-Patch CM was successfully passed its nonclinical testing. The testing activities included:

- Biocompatibility evaluation per ISO 10993-1 Fourth edition 2009 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.
- Electromagnetic Compatibility per 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.
- Electrical Safety per AAMI/ANSI ES60601-1:2005/(R) 2012 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
- Ambulatory ECG testing per ANSI/AAMI/IEC 60601-2-47:2012 (60601-2-47); Medical electrical equipment – Part 2-47: Requirements for the safety, including essential performance, of ambulatory electrocardiographic systems
- Software verification and validation testing

Clinical Testing Summary [807.92(b)(2)]

No clinical testing is required to demonstrate substantial equivalence to the predicate eCordum Cardiac Monitor (K193296).

Conclusions [807.92(b)(3)]

The V-Patch CM 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 V-Patch CM is substantially equivalent to its predicate device, the eCordum Cardiac Monitor (K193296).