January 6, 2023

CardiacSense
% Oxana Pantchenko
Sr. Engineer
RQM+
2251 San Diego Ave.
Ste B-257
San Diego, California 92110

Re: K221260
Trade/Device Name: CSF-3
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II
Product Code: DPS, DQA, DXH,
Dated: December 6, 2022
Received: December 7, 2022

Dear Oxana Pantchenko:

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 Shruti N. Mistry -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)*
K221260

Device Name
CSF-3

Indications for Use *(Describe)*
The CSF-3 is intended to record, store, transfer, and display single-channel electrocardiogram (ECG) rhythms. The ECG signal is for quality checks of the data and for manual interpretation of heart rate. The CSF-3 is also indicated for use in measuring and displaying functional oxygen saturation of arterial hemoglobin (SpO2). The CSF-3 is for adult patients and health-conscious individuals in hospitals, clinics, long-term care facilities, and homes. The CSF-3 is a prescription device and should be used under the care of a physician. CSF-3 does not provide any alarms. It is not intended for pediatric use or use in critical care settings.

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

DATE PREPARED
January 5, 2023

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DEVICE INFORMATION
Proprietary Name/Trade Name: CSF-3
Regulation: 21 CFR 870.2340 - Electrocardiograph
Class: 2
Product Codes: DPS, DQA, DXH
Premarket Review: Cardiac Electrophysiology, Diagnostics, and Monitoring Devices (DHT2A)
Review Panel: Cardiovascular

PREDICATE DEVICE IDENTIFICATION
The CSF-3 is substantially equivalent to the following predicate:

510(k) Number	*Predicate Device Name / Manufacturer*	*Primary Predicate*
K201456	Scan Monitor / Withings	✓

The predicate device has not been subject to a design related recall.

DEVICE DESCRIPTION
The CSF-3 is a non-invasive system consisting of software, hardware and mechanical components that enables the user to measure electrocardiography (ECG) and oxygen saturation of arterial hemoglobin (SpO2).

The CSF-3 is intended to record, store, transfer, and display single-channel electrocardiogram

(ECG) rhythms. The ECG signal is for quality checks of the data and for manual interpretation of heart rate. The CSF-3 is also indicated for use in measuring and displaying functional oxygen saturation of arterial hemoglobin (SpO2). The CSF-3 is intended for the spot-checking of adult patients and health-conscious individuals in hospital clinics, long-term care facilities, and homes. The CSF-3 is a prescription device and should be used under the care of a physician. The CSF-3 does not provide any alarms. It is not intended for pediatric use or use in critical care settings.

The CSF-3 consists of 3 main components:
1) CS Watch 3 with CSF-3 Watch firmware ("Watch"): The Watch is a wrist worn device embedded with non-invasive sensors. The Watch includes firmware that activates the sensors, synchronizes the data sampled by the sensors, processes the data, stores the processed data in non-volatile memory, and provides the data to the user. The processed data is transferred to the Mobile App via a secured BLE communication channel. In addition, the watch sends real-time raw data signals to the Mobile App.
2) CSF-3 Mobile Application ("Mobile App"): The Mobile App works on both Android OS and iOS. The Mobile App communicates with the Watch via BLE and to the Cloud App via HTTPS, thus acting as the Watch gateway to the Cloud App. The Mobile App caches the processed data from the Watch and transfers it to the Cloud App. It allows the user to conveniently view the measurement results and real time raw data. The Mobile App provides the user with the capability of creating an on-demand report and sharing it using 3rd party sharing applications.
3) CSF-3 Cloud Application ("Cloud App"): The Cloud App securely stores the user and processed data over designated databases. It provides the mechanism of creating and sending periodical reports which are sent to the user's email both automatically and on-demand. The Cloud App has the following features.

INDICATIONS FOR USE

The CSF-3 is intended to record, store, transfer, and display single-channel electrocardiogram (ECG) rhythms. The ECG signal is for quality checks of the data and for manual interpretation of heart rate. The CSF-3 is also indicated for use in measuring and displaying functional oxygen saturation of arterial hemoglobin (SpO2). The CSF-3 is for adult patients and health-conscious individuals in hospitals, clinics, long-term care facilities, and homes. The CSF-3 is a prescription device and should be used under the care of a physician. CSF-3 does not provide any alarms. It is not intended for pediatric use or use in critical care settings.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

The CSF-3 has the same intended use as the Scan Monitor by Withings for measuring and displaying physiological parameters. The CSF-3 proposed indications for use are not identical to the ones for the Scan Monitor, however the CSF-3 is indicated for a subset of them. CSF-3 is not intended for detecting or displaying atrial fibrillation or any other arrhythmias. Additionally, the CSF-3 is intended as a prescription use only device whereas the predicate is intended for over-

the-counter (OTC) use and prescription use when used for detecting atrial fibrillation. The prescription use status of the CSF-3 device means that it will be used under the supervision of a healthcare provider and thus presents a lower risk than OTC use and does not present any new or different risks as compared to the predicate devices when used as cleared for OTC use.

The CSF-3 uses similar technology as the Scan Monitor predicate device in recording, storing, and displaying ECG waveforms. Both devices are 1-lead ECGs and include three electrodes (2 contacting the skin and one reference electrode) and transmit the data wirelessly (via Bluetooth) to a dedicated mobile app. The CSF-3 and Scan Monitor, the predicate device, use the same technology to measure, record, and display SpO2. The predicate device measures SpO2 through the sensors located on the wrist, whereas the CSF-3 is a finger oximeter. This minor difference does not raise new questions of safety or effectiveness. Measurement of SpO2 from the finger is similar to multiple other cleared fingertip wrist oximeters, including "Massimo Radical 7" cleared under K061204 and Nellcor N595 cleared under K123581. Although there is a difference in the anatomical sites, PPG sensors are commonly worn on the fingers due to the high signal amplitude. The research shows that the fingers, palm, face, and ears offer much higher perfusion values compared with the other measurement sites. Moreover, both devices were tested against the A-line as a reference and not against each other and both achieved the necessary clinical performance. The minor differences in the technology do not raise new questions of safety or effectiveness. Non-clinical and clinical testing demonstrate that the CSF-3 is as safe and effective as the Withings Scan Monitor predicate device in measuring and displaying ECG and SpO2.

Based on the testing performed, including non-clinical and clinical data collected, it can be concluded that the CSF-3 device does not raise new issues of safety or effectiveness compared to the Scan Monitor predicate device. The similar indications for use, technological characteristics, and performance characteristics for the proposed CSF-3 are assessed to be substantially equivalent to the Scan Monitor predicate device. CardiacSense believes that the CSF-3 is substantially equivalent to the Scan Monitor predicate device.

SUMMARY OF NON-CLINICAL TESTING

Biocompatibility Testing

Based on the device type and contact duration and FDA's *Guidance for Industry and Food and Drug Administration Staff – Use of International ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*", the following biocompatibility tests be performed: in vitro cytotoxicity, irritation, and skin sensitization. The test article extract showed no evidence of causing cell lysis or toxicity. The test article extract met the requirements of the test since the grade was less than a grade 2 (mild reactivity). Next, the test article extracts showed no evidence of causing delayed dermal contact sensitization. The test article was not considered a sensitizer in the guinea pig maximization test. Lastly, there was no erythema and no edema observed on the skin of the animals treated with the SC test

article extract. The Primary Irritation Index for the SC test article extract was calculated to be 0.0. The irritation response of the SC test article extract was categorized as negligible. There was no erythema and no edema observed on the skin of the animals treated with the SO test article extract. The Primary Irritation Index for the SO test article extract was calculated to be 0.0. The irritation response of the SO test article extract was categorized as negligible.

EMC, Wireless, Electrical, Mechanical and Thermal Testing

The CSF-3 System was evaluated for safety against the following standards:
1) ANSI/AAMI IEC/EN 60601- 1:2005/(R)2012 + A1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
2) IEC 60601-2-47:2012 Medical electrical equipment - Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic Systems
3) IEC 62133-2:2017 - Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary lithium cells, and for batteries made from them, for use in portable applications - Part 2: Lithium Systems
4) IEC 60601-1-2:2014 Ed. 4 - Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
5) IEC 60601-1-11:2015 Medical electrical equipment -- Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical Systems used in the home healthcare environment
6) IEC 62472:2006 Safety analysis performed based on IEC 62471 or other lamp optical safety standards
Applicable requirements have been met.

Bench Testing

The performance of the QRS algorithm was evaluated against three databases following the requirements stated in the IEC-60601-2-47 standard. The QRS statistics were calculated per recording and per database. The per-database statistics were calculated as both gross and average.

The QRS detection performance is above 98% for both sensitivity and PPV parameters for the MIT-BIH Arrhythmia and AHA databases. In the more challenging MIT-BIH Noise Stress database, the sensitivity and PPV were above 93%.

The HR RMS accuracy varies between 1-2% for the MIT-BIH Arrhythmia and AHA databases but dropped to slightly above 3% for the more challenging MIT-BIH Noise Stress database.

The results of these tests indicate that the CSF-3 is substantially equivalent to the predicate device.

SUMMARY OF CLINICAL TESTING

The ECG performance in measuring HR was validated in a clinical study by comparing the CSF-3 to a Holter. The study included 52 subjects and a total of 23,579 samples resulted with sensitivity of 99.6% and false detection rate of 0.54% and ARMS of 1.54 BPM.

The Pulse Oximeter Testing was conducted in the Hypoxia Research Laboratory, Department of Anesthesia Perioperative Care, University of California at San Francisco (UCSF) in compliance with the ISO 80601-2-61:2017 standard. The clinical study with n=234 samples, the SpO2 range was validated to be from 70% to 100% with accuracy of 2.96%.

CONCLUSION

Based on the testing performed, it can be concluded that the CSF-3 does not raise new issues of safety or effectiveness compared to the predicate device. The similar indications for use, technological characteristics, and performance characteristics for the proposed CSF-3 are assessed to be substantially equivalent to the predicate device.