May 2, 2024

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

Re: K232445
Trade/Device Name: CSF-4
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II
Product Code: DPS, DQA, DXH
Dated: April 1, 2024
Received: April 2, 2024

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 (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
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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)*
K232445

Device Name
CSF-4

Indications for Use *(Describe)*
The CSF-4 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-4 also measures, records and displays pulse rate.

The CSF-4 is also indicated for use in measuring and displaying functional oxygen saturation of arterial hemoglobin (SpO2). The CSF-4 is for adult patients and health-conscious individuals in hospitals, clinics, long-term care facilities, and homes. The CSF-4 is a prescription device and should be used under the care of a physician. CSF-4 does not provide any alarms. It is not intended for pediatric use or use in critical care settings. The device is not intended to provide outputs during periods of motion.

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.

510(k) Summary

DATE PREPARED
May 1st, 2024

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DEVICE INFORMATION
Name: CSF-4
Regulation Number: 870.2340 - Electrocardiograph Class: 2
Product Code: DPS, DQA, DXH
Premarket Review: Cardiac Electrophysiology, Diagnostics, and Monitoring Devices (DHT2A) Review Panel: Cardiovascular

PREDICATE/REFERENCE DEVICE IDENTIFICATION
The CSF-4 is substantially equivalent to the following predicate and reference devices:

510(k) Number	*Predicate Device Name / Manufacturer*	*Primary Predicate*
K221260	CSF- 3 / CardiacSense	✓
K181352	Loop System / Spry Health, Inc.	

The predicate devices have not been subject to a design related recall.

DEVICE DESCRIPTION
The CSF-4 is a non-invasive system comprised of software, hardware and mechanical components that enables the user to measure electrocardiography (ECG) and oxygen saturation of arterial hemoglobin (SpO2), as well as measuring pulse rate using photoplethysmography (PPG).
CSF-4 is a single-patient use, wearable monitoring device that collects intermittent data of physiological parameters, when little to no motion is detected.

The CSF-4 is comprised of 3 main components;
1) CS Watch 3 with CSF-4 Watch firmware ("Watch"): The CS Watch 3 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-4 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 application. The Mobile App caches the processed data from the watch and transfers it to the cloud application. 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-4 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.

INDICATIONS FOR USE

The CSF-4 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-4 also measures, records and displays pulse rate.
The CSF-4 is also indicated for use in measuring and displaying functional oxygen saturation of arterial hemoglobin (SpO2). The CSF-4 is for adult patients and health-conscious individuals in hospitals, clinics, long-term care facilities, and homes. The CSF-4 is a prescription device and should be used under the care of a physician. CSF-4 does not provide any alarms. It is not intended for pediatric use or use in critical care settings. The device is not intended to provide outputs during periods of motion.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

The CSF-3 and the CSF-4 devices have the same indications for use in terms of measuring and displaying a number of physiological parameters. The CSF-4 proposed indications for use encompass those of the CSF-3 indications for use and add on an additional method for measuring heart rate/pulse rate using PPG. Currently, the CSF-3 device measures heart rate by ECG only. The CSF-4 is proposing to also measure heart rate by PPG. Additionally, CardiacSense proposes to use the Loop System by Spry Health, Inc. as a reference device to demonstrate substantial equivalence regarding additional method for measuring heart rate/pulse rate using PPG.

The CSF-3 and the CSF-4 use the same technology 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 the CSF-4 use the same technology to measure, record, and display SpO2. Both devices measure SpO2 through a patient's finger. Lastly, the CSF-4 and the Loop System, both measure heart rate/pulse rate by using skin contacting sensors, utilizing PPG technology, worn around patient's wrist.

Based on the testing performed, including non-clinical and clinical data collected, it can be concluded that the CSF-4 device does not raise new issues of safety or effectiveness compared to the CSF-3 predicate device. The similar indications for use, technological characteristics, and performance characteristics for the proposed CSF-4 are assessed to be substantially equivalent to the CSF-3 predicate device. CardiacSense believes that the CSF-4 is substantially equivalent to the CSF-3 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 were performed: in vitro cytotoxicity, irritation, and skin sensitization.

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 statistic was calculated per recording and per database. The per-database statistic was calculated as both gross and average, as discussed above in detail.

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 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%.

The ECG and the PPG were tested in Fairview Research Center of the University of Minnesota. The study was reviewed and accepted by the Agency as part of the submission of CSF-3. The ECG was

validated with the following performance, sensitivity of 99.59% and false detection rate of 0.54%. The PPG was validated with the following performance, sensitivity of 99.78% and false detection rate of 0.03%.

CONCLUSION

Based on the testing performed, it can be concluded that the CSF-4 does not raise new issues of safety or effectiveness compared to the predicate devices. The similar indications for use, technological characteristics, and performance characteristics for the proposed CSF-4 are assessed to be substantially equivalent to the predicate device.