July 23, 2021

SurePulse Medical Limited
% Allison Komiyama
Prinicipal Consultant
AcKnowledge Regulatory Strategies, LLC
2251 San Diego Ave, Suite B-257
San Diego, California 92110

Re: K201887
Trade/Device Name: VS Newborn Heart Rate Monitor
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: July 6, 2020
Received: July 8, 2020

Dear Allison Komiyama:

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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K201887

Device Name
VS Newborn Heart Rate Monitor

Indications for Use *(Describe)*

The VS Newborn Heart Rate Monitor is indicated for the continuous monitoring of heart rate in neonatal patients. The device uses reflectance photoplethysmography to determine heart rate. The sensor is integrated into a cap placed on the head of the patient. The VS Newborn Heart Rate Monitor is intended for use under the direct supervision of a licensed healthcare practitioner, or by personnel trained in proper use of the equipment in a professional healthcare facility.

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

DATE PREPARED
July 6, 2020

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DEVICE INFORMATION

Proprietary Name/Trade Name:	VS Newborn Heart Rate Monitor
Common Name:	Oximeter
Regulation Number:	21 CFR 870.2700
Class:	II
Product Code:	DQA
Premarket Review:	Anesthesiology
Review Panel:	Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices (OHT1) ENT, Sleep Disordered Breathing, Respiratory and Anesthesia Devices (DHT1C)

PREDICATE DEVICE IDENTIFICATION
The VS Newborn Heart Rate Monitor is substantially equivalent to the following predicate:

510(k) Number	*Predicate Device Name / Manufacturer*	*Primary Predicate*
K091241	Masimo Rainbow SET® Rad 87 CO-Oximeter and Accessories / Masimo Corporation	✓

510(k) Summary

DEVICE DESCRIPTION

The VS Newborn Heart Rate Monitor is a non-invasive device intended to continuously monitor heart rate (HR) in neonates immediately after delivery and in newborn intensive care units (NICU). The VS Newborn Heart Rate Monitor measures HR using reflectance photoplethysmography (PPG). The sensor is integrated into a single-use soft cap placed on the head of the newborn such that the sensor contacts the forehead of the newborn. The PPG signal and HR are displayed on the monitor. The VS Newborn Heart Rate Monitor is designed for use in hospitals.

INDICATIONS FOR USE

The VS Newborn Heart Rate Monitor is indicated for the continuous monitoring of heart rate in neonatal patients. The device uses reflectance photoplethysmography to determine heart rate. The sensor is integrated into a cap placed on the head of the patient. The VS Newborn Heart Rate Monitor is intended for use under the direct supervision of a licensed healthcare practitioner, or by personnel trained in proper use of the equipment in a professional healthcare facility.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

SurePulse believes that the VS Newborn Heart Rate Monitor is substantially equivalent to the predicate device based on the information summarized here:

The subject device has a similar design and uses similar materials as the device cleared in K091241. The subject device has an equivalent intended use and similar technological characteristics as the device cleared in K091241. Unlike the predicate device that uses both green visible light and infrared light to measures heart rate and pulse oximetry, the VS Newborn Heart Rate Monitor only uses green visible light to determine heart rate. Unlike the predicate which is indicated for neonates, pediatric, infant, and adult populations, the VS Newborn Heart Rate Monitor is indicated for neonates only. To address the differences in technological characteristics, the subject device underwent biocompatibility testing, performance bench testing, and a clinical study.

SUMMARY OF NON-CLINICAL TESTING

No FDA performance standards have been established for the VS Newborn Heart Rate Monitor.

Patient-contacting material was subjected to biocompatibility testing in compliance with ISO 10993-1 *Biological evaluation of medical devices – Part 1: Evaluation and testing with a risk management process.*

The following tests were performed to demonstrate safety based on current industry standards:

- Basic safety and essential performance (per ISO 60601-1)
- Electromagnetic disturbances (per IEC 60601-1-2)
- Usability (per IEC 62366-1 and IEC 60601-1-6)
- Safety requirements for batteries (per IEC 62133)
- Basic safety and essential performance of pulse oximeter equipment (per ISO 80601-2-61)
- LED safety (per IEC 62471)
- Algorithm (per JIS T 1303)

The results of these tests indicate that the VS Newborn Heart Rate Monitor is substantially equivalent to the predicate devices.

SUMMARY OF CLINICAL TESTING

The VS Newborn Heart Rate Monitor underwent clinical testing at the Nottingham University Hospitals NHS Trust, in Nottingham, England. Three phases of the study were 1) assessing the thermal properties of the cap component 2) testing device function with NICU newborns, and 3) testing device function with C-section newborns. The study assessed multiple endpoints including primary, secondary, and safety endpoints. The primary endpoint of the study was to demonstrate the reliability and accuracy (i.e., Bland-Altman limits of agreement) of the subject device. The secondary endpoints included acquisition time and to obtain feedback about the subject device from mothers and healthcare professionals. Finally, there were two safety endpoints that were also considered throughout the study: any sign of skin damage due to the device, and any other unanticipated adverse events attributed to the device. The subject device was compared to ECG electrodes (K024264) and the LNCS pulse oximetry sensors (K110723). Those two devices were connected to the CARESCAPE Monitor B450 (132533) which was connected to a laptop computer. The subject device was connected to the same laptop computer and all data recorded synchronously. In total, 74 newborns, 13 mothers, and 40 healthcare professionals participated in the study. The subject device was found to maintain temperature as well as the standard of care and was as reliable and accurate as the devices it was compared to. Furthermore, there were no signs of skin irritation or adverse events therefore demonstrating that the VS Newborn Heart Rate Monitor is safe.

CONCLUSION

Based on the testing performed, including biocompatibility, electrical safety, LED safety, and clinical testing, it can be concluded that the subject device 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 VS Newborn Heart Rate Monitor are assessed to be substantially equivalent to the predicate device.