March 8, 2022

Stryker Sustainability Solutions
Mia Brown
Senior Regulatory Affairs Specialist
1810 West Drake Drive
Tempe, Arizona 85283

Re: K211138
Trade/Device Name: Reprocessed Pulse Oximeter Sensor Models: (D-25), (D-25L), (D-20), (N-25), (I-20), (Max-A), (Max-AL), (Max-P), (Max-N), (Max-I).
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: NLF
Dated: February 10, 2022
Received: February 11, 2022

Dear Mia Brown:

(NOTE: Reprocessed SUD device types require a separate attachment of the list of all models cleared in the submission. A corrected SE letter will be required if the attachment is omitted.)

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,

Todd Courtney
Assistant Director
DHT1C: Division of Sleep Disordered
Breathing, Respiratory and
Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental 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)*
K211138

Device Name
Reprocessed Pulse Oximeter Sensor Models: (D-25), (D-25L), (D-20), (N-25), (I-20), (Max-A), (Max-AL), (Max-P), (Max-N), (Max-I).

Indications for Use *(Describe)*
The sensor is indicated for single patient use for continuous noninvasive arterial oxygen saturation and pulse rate 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.

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510(k) Summary

As required by 21 CFR 807.92

Contact Details

Applicant Name	Stryker Sustainability Solutions
Applicant Address	1810 West Drake Drive Tempe, AZ 85283
Applicant Contact	Mia Brown
Applicant Contact Email	mia.brown1@stryker.com

Device Name

Device Trade Name	Reprocessed Pulse Oximeter Sensor Models: (D-25), (D-25L), (D-20), (N-25), (I-20), (Max-A), (Max-AL), (Max-P), (Max-N), (Max-I).
Common Name	Oximeter
Classification Name	Oximeter, Reprocessed
Regulation Number	870.2700
Product Code	NLF

Legally Marketed Predicate Devices

Predicate #	*Predicate Trade Name (Primary Predicate is listed first)*	*Product Code*
K042316	Vanguard Reprocessed Pulse Oximeter Sensors	NLF
K012344	Vanguard Reprocessed Pulse Oximeter Sensors	NLF
K012891	OxiMax Pulse Oximetry System with N-595 Pulse Oximeter and OxiMax Sensors and Cables	DQA
K993637	N-395 Pulse Oximeter, with extended device claims	DQA

Device Description Summary

In a clinical setting, a pulse oximeter sensor measures the oxygen saturation of arterial blood (SpO2). A pulse oximeter sensor is composed of a light emitting diode (LED) and a sensor that are placed on opposite sides of a patient's finger or foot. The LED contains a red light and an infrared light that are differentially absorbed by oxygenated and deoxygenated hemoglobin. Based on the relative absorption of the two wavelengths that is determined by the sensor, the POX determines the relative amount of oxygenated and deoxygenated hemoglobin, which is calculated as SpO2. In order to make the SpO2 calculation independent of skin color, finger size, etc., the pulse oximeter sensor uses only the time varying light absorption component generated by the patient's pulse. The sensor also uses the period of pulsation to measure patient pulse rate. The pulse oximeter can estimate the amount of oxygen in the blood without having to draw a blood sample.

The primary components of an oxygen transducer, or Pulse Oximeter (POX) Sensor, are light-emitting diodes (red and infrared LED) and a photo sensor. These components (with their wiring system) are embedded within a taping system designed for wrapping the POX Sensor around a patient's finger, foot, or hand so that the LED and photo sensor are directly opposite to each other. As the lights are emitted and received across a vascular bed, the rates of absorption at the two wavelengths vary depending upon the ratios of oxygenated and deoxygenated hemoglobin within the blood.

The proposed devices of this submission do not differ from the predicate device. The only difference is that the proposed devices will be exposed to vaporized hydrogen peroxide for sterilization instead of ethylene oxide.

Intended Use/Indications for Use

The sensor is indicated for single patient use for continuous noninvasive arterial oxygen saturation and pulse rate monitoring.

Indications for Use Comparison

The indications for use for the subject device are the same as those of the predicate device, with the exception that the neonatal indication has been removed from the Max-N and N-25 models.

Technological Comparison

The design of the reprocessed device is the same as the predicate device. The indications for use does not change from the predicate device (K042316, K012344), with the exception that the neonatal indication has been removed from the Max-N and N-25 models. The same standard mechanical design and sizes and equivalent materials are utilized. There are no changes to the claims, clinical applications, or performance specifications.

The subject device and the predicate device have the same technological characteristics, i.e., they have the same:

- intended use;
- principle of operation;
- form factor and components;
- measurement application sites;
- performance specifications;
- environmental and mechanical specifications

Principle of Operation

The principle of operation of pulse oximetry is based upon the fundamental principle that hemoglobin bound to oxygen (oxyhemoglobin) and hemoglobin unbound to oxygen (deoxyhemoglobin) vary in the absorption of different wavelengths of the light and the absorptions can be used to estimate SpO2 and pulse rate. The mechanism by which this process occurs is the use of red and infrared wavelengths of light delivered by an emitter and the detection of the signal from the light absorption of oxygenated blood and deoxygenated blood to determine functional oxygen saturation of hemoglobin (SpO2).

Mechanism of Action for Achieving the Intended Effect

The Reprocessed Pulse Oximeter Sensor provides the intended effect equivalent to the previously cleared pulse oximeter sensor in that it utilizes an optical sensor that is applied to the patient's finger or toe through which light is transmitted to the photodetector that detects the signal transmission. The signal transmission is processed by the Pulse Oximeter to provide SpO2 and pulse rate.

Non-Clinical and/or Clinical Tests Summary & Conclusions

To support the substantial equivalence of product performance after being sterilized by vaporized hydrogen peroxide to that of the predicate devices, non-clinical bench simulation testing was conducted using a stand-in device. The stand-in device allows for SpO2 sensor verification by passing the light source of the pulse oximeter sensor (LED) through one side of the stand-in with the signal transmission measured by the photocell (photo-detector) of the pulse oximeter sensor on the opposing side of the stand-in.

A functional pulse oximeter sensor when connected to a pulse oximeter console will have the ability to monitor SpO2 and Pulse Rate. Bench and laboratory testing was conducted to determine whether a pulse oximeter sensor is functional and is assessed by performing continuity and sensitivity testing. This included the following tests:

- Continuity testing to verify there are no open circuits and the current along the path of a circuit is continuous
- Sensitivity testing to detect the signal transmission between the photodiode and the LED (light emitting diode)

Additional performance testing of this submission references data submitted in previously cleared 510(k)s K042316 and K012344.

All reprocessed pulse oximeter sensors materials that are normally in contact with the patient are removed and replaced with medical grade adhesive tape during reprocessing by Stryker Sustainability Solutions. The reprocessed pulse oximeter sensors meet biocompatibility requirements of ANSI/AAMI/ISO 10993-1: 2009: Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process for surface contacting devices with prolonged exposure (> 24 hours, but less than 30 days) with skin.

Clinical Testing

Stryker Sustainability Solutions performed the clinical validation testing of the SpO2 performance under no motion on healthy, adult volunteers in the range of 70% to 100%. The ARMS for SpO2 under no motion was found to be 1.62% and 1.56% for woven and non-woven tape, respectively, over the range of 70-100%.

The results of the non-clinical and clinical testing demonstrate that all requirements and performance specifications were satisfied and support the subject device is substantially equivalent to its predicate.

The subject device has the same intended use as the proposed predicate and the differences in technological features do not raise different questions of safety and effectiveness. Based on a comparison of the intended use/indications for use, technological characteristics, and performance data to the predicate devices, the subject device is equivalent to the predicate device.