December 4, 2022

Stryker Sustainability Solutions
Michael Wong
Regulatory Affairs Specialist
1810 W Drake Drive
Tempe, Arizona 85283

Re: K222019
Trade/Device Name: Reprocessed RD SET Adt Pulse Oximeter Sensor (4000), Reprocessed RD SET Pdt Pulse Oximeter Sensor (4001), Reprocessed RD SET Inf Pulse Oximeter Sensor (4002), Reprocessed RD SET Adt Pulse Oximeter Sensor (4003)
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: NLF
Dated: November 4, 2022
Received: November 4, 2022

Dear Michael Wong:

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,

James J. Lee -S

James J. Lee, Ph.D.
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)*
K222019

Device Name
Reprocessed RD SET Adt Pulse Oximeter Sensor (4000); Reprocessed RD SET Pdt Pulse Oximeter Sensor (4001); Reprocessed RD SET Inf Pulse Oximeter Sensor (4002); Reprocessed RD SET Adt Pulse Oximeter Sensor (4003)

Indications for Use *(Describe)*
The Reprocessed RD SET pulse oximeter sensors are indicated for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (measured by an SpO2 sensor) for use with adult, pediatric, and infant patients during non-motion conditions, and for patients who are well or poorly perfused in hospitals and hospital-type facilities.

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

Submitter:

Stryker Sustainability Solutions
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Tempe, AZ 85283

Contact:

Michael Wong
Regulatory Affairs Specialist
(480) 213-1342
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Device Name:

Device Trade Name:

Reprocessed RD SET® Adt Pulse Oximeter Sensor (4000);
Reprocessed RD SET® Pdt Pulse Oximeter Sensor (4001);
Reprocessed RD SET® Inf Pulse Oximeter Sensor (4002);
Reprocessed RD SET® Adt Pulse Oximeter Sensor (4003)

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
K211140	Reprocessed Masimo Pulse Oximeter (1859 Adult O2 Transducer), Reprocessed Masimo Pulse Oximeter (1860 Pediatric O2 Transducer), Reprocessed Masimo Pulse Oximeter (1861 Infant O2 Transducer), Reprocessed Masimo Pulse Oximeter (1862 Adult O2 Transducer), Reprocessed Masimo Pulse Oximeter (2317 Adult O2 Transducer), Reprocessed Masimo Pulse Oximeter (2319 Infant O2 Transducer), Reprocessed Masimo Pulse Oximeter (2320 Adult O2	NLF

	Transducer), Reprocessed Masimo Pulse Oximeter (2328 Infant O2 Transducer), Reprocessed Masimo Pulse Oximeter (2329 Adult O2 Transducer)	
K180046	Masimo Rad-97 and Accessories	DQA

Device Description Summary:

In a clinical setting, a pulse oximeter sensor measures the oxygen saturation of arterial blood (SpO_2). 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 SpO_2. In order to make the SpO_2 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.

As part of the reprocessing manufacturing process, we collect used devices from hospitals, replace required components, clean the devices and test the functional performance of the devices to ensure they meet or exceed regulatory requirements and the expectations of our customers.

Indications for Use:

The Reprocessed RD SET® pulse oximeter sensors are indicated for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate (measured by an SpO_2 sensor) for use with adult, pediatric, and infant patients during non-motion conditions, and for patients who are well or poorly perfused in hospitals and hospital-type facilities.

Indications for Use Comparison:

The indications for use for the subject device are the same as those of the predicate devices, with the exceptions that the neonatal indication has been removed from the 4003 model and

motion and mobile/home environment indications have been removed from the 4000, 4001, 4002, and 4003 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 devices (K211140 and K180046), with the exception that the neonatal indication has been removed from the 4003 model and the motion and mobile/home environment indications have been removed from the 4000, 4001, 4002, and 4003 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 devices have the same technological characteristics, i.e., they have the same:

- intended use;
- principle of operation;
- form factor;
- 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 SpO_2 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 the functional oxygen saturation of hemoglobin (SpO_2).

Mechanism of Action for Achieving the Intended Effect

The Reprocessed RD SET® 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 SpO_2 and pulse rate.

Non-Clinical and/or Clinical Tests Summary:

To support the substantial equivalence of product performance after being reprocessed and decontaminated by vaporized hydrogen peroxide to that of the predicate devices, non-clinical bench testing was conducted using a stand-in device. The stand-in device allows for SpO_2 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 SpO_2 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
- Sensitivity testing
- Clinical laboratory testing
- Non-clinical bench testing (SpO_2, Pulse Rate, Monitor Compatibility)

Stryker Sustainability Solutions performed the clinical validation testing of the SpO_2 performance under no motion conditions on healthy, adult volunteers in the range of 70% to 100%. The A_{rms} (average root means squared) for SpO_2 under no motion conditions was found to be 2.04% and 2.11% for non-woven and woven tape, respectively, over the range of 70-100%. These A_{rms} results are less than 3.0% and are in conformance with Clause 201.12.1.101.1 of ISO 80601-2-61:2011 and Table 3 of "Pulse Oximeters - Premarket Notification Submissions [510(k)s]: Guidance for Industry and Food and Drug Administration Staff."

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 devices.

Comparison Table:

Please see Pages 5-7 for a table comparing the subject device with the primary (K211140) and secondary (K180046) predicate devices.

Conclusion:

The subject device has the same intended use as the proposed predicates 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 devices. The results from bench and laboratory testing demonstrate that the Reprocessed RD SET® Pulse Oximeter Sensor is as safe and effective as the identified legally marketed predicate devices as described herein.

Description	Subject Device		K180046 Secondary Predicate		K211140 Primary Predicate		Comparison
Intended Patient Population	4000	Adult	4000	Adult	1859, 2317, 1862, 2320, 2329	Adult	Stryker Sustainability Solutions will not make claims for neonatal use.
	4001	Pediatric	4001	Pediatric			
	4002	Infant	4002	Infant	1860	Pediatric	
	4003	Adult	4003	Adult/Neonatal	1861, 2319, 2328	Infant	
Patient Weight Range	• Adult: >30 kg (4000) • Adult: >40 kg (4003) • Pediatric: 10 – 50 kg (4001) • Infant: 3 – 20 kg (4002)		• Adult: >30 kg (4000) • Adult: >40 kg (4003) • Pediatric: 10 – 50 kg (4001) • Infant: 3 – 20 kg (4002) • Neonate: <3 kg (4003)		• Adult: >30 kg (Adtx, Adtx-3) • Pediatric: 10 – 50 kg (Pdtx, Pdtx-3) • Infant: 3 – 20 kg (Inf, Inf-L, Inf-3)		Stryker Sustainability Solutions will not make claims for neonatal use.
Intended Application Site	4000	Middle or ring finger	4000	Middle or ring finger of non-dominant hand	1859, 2317	Finger	As stated
	4001	Middle or ring finger	4001	Middle or ring finger of non-dominant hand	1860	Finger or toe	
	4002	(3 – 10 kg): Great toe, toe next to great toe, or thumb (10 – 20 kg): Middle or ring finger	4002	(3 – 10 kg): Great toe, toe next to great toe, or thumb (10 – 20 kg): Middle or ring finger of non-dominant hand	1861, 2319, 2328	Thumb or great toe	
	4003	(>40 kg): Middle or ring finger	4003	(<3 kg): Foot or across the palm and back of the hand (>40 kg): Middle or ring finger of non-dominant hand	1862, 2320, 2329	Adult finger or toe	
Indications for Use	The reprocessed RD SET Disposable Pulse Oximeter Sensors are indicated for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (measured by an SpO2 sensor) for use with adult, pediatric, and infant patients during no motion conditions, and for patients who are well or poorly perfused in hospitals and hospital-type facilities.		The RD SET® Series disposable sensors are indicated for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (measured by an SpO2 sensor) for use with adult, pediatric, infant, and neonatal patients during both no motion and motion conditions, and for patients who are well or poorly perfused in hospitals, hospital-type facilities, mobile, and home environments.		INDICATIONS – When used with Masimo SET Radical: Reprocessed Masimo Pulse Oximeter sensor is indicated for use in continuous noninvasive arterial oxygen saturation and pulse rate monitoring.		Stryker Sustainability Solutions will not make claims for use in home or mobile environments or for use during motion conditions.
Contra-Indications	The reprocessed RD SET sensors are contraindicated for patients who exhibit		The RD SET sensors are contraindicated for patients who		Reprocessed Masimo Pulse Oximeter sensor should not be used in patients who		Same

	allergic reactions to foam rubber products and/or adhesive tape.	exhibit allergic reactions to foam rubber products and/or adhesive tape.	exhibit allergic reactions to foam rubber products and/or adhesive tape.	
Form Factor	• Adhesive Bandage	• Adhesive Bandage	• Adhesive Bandage	Same
Single Use	Yes	Yes	Yes	Same
Use Environment	Hospitals and hospital-type facilities	Hospitals, hospital-type facilities, mobile, and home environments	Hospitals and hospital-type facilities	Stryker Sustainability Solutions will not make claims for use in home and mobile environments.
Sterility	Non-sterile	Non-sterile	Non-sterile	Same
Expiration Date	No	No	No	Same
Uses	Single patient use	Single patient use	Single patient use	Same
Number of Reprocessing Cycles	4	N/A	4	As stated
Laminate (replaced or saved)	The laminate that encloses the optical components is replaced.	N/A	The laminate that encloses the optical components is replaced.	Same
Optical Design	Transmissive Sensor	Transmissive Sensor	Transmissive Sensor	Same
Performance Specifications				
Saturation Accuracy, No Motion	2.2%	1.5%	±2%	As stated
Saturation Accuracy, Motion	N/A	1.5%	N/A	As stated
Saturation Accuracy, Low Perfusion	2.5%	2%	N/A	As stated
Pulse Rate Accuracy, No Motion	±3 bpm (30-200 bpm)	±3 bpm (25-240 bpm)	±3 bpm	As stated
Pulse Rate Accuracy, Motion	N/A	±5 bpm (25-240 bpm)	N/A	As stated
Pulse Rate Accuracy, Low Perfusion	±3 bpm (30-200 bpm)	±3 bpm (25-240 bpm)	N/A	As stated
Safety Specifications (e.g., electrical, mechanical, environmental)				
Electrical	Universal 100-240 VAC to DC multi-voltage power supply	Universal 100-240 VAC to DC multi-voltage power supply	Universal 100-240 VAC to DC multi-voltage power supply	Same
Environmental				
Operating Temperature:	5°C to 40°C, ambient humidity	5°C to 40°C, ambient humidity	41°F to 104°F (5°C to 40°C)	As stated
Storage Temperature:	-20 °C to +50 °C, ambient humidity	-20 °C to +40 °C, ambient humidity	-40°F to +158°F (-40°C to +70°C)	As stated
Operating Humidity:	15% to 95%, non-condensing	10% to 90%, non-condensing	5% to 95%, non-condensing	As stated
Features (e.g., alarms, display and indicators, modes)				
Alarms	N/A	Audible and visual alarms for high and low saturation and pulse rate.	N/A	Stryker Sustainability Solutions does not provide or reprocess the display. Therefore, the alarms remain the same.
Displays & Indicators	N/A	Data display: %SpO2, pulse rate, alarm status, alarm silenced status, AC power, Signal IQ/pleth bar, perfusion index bar, battery status	N/A	Stryker Sustainability Solutions does not provide or reprocess the display. Therefore, the display characteristics remain the same.