October 22, 2024

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

Re: K241758
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, DQA
Dated: September 12, 2024
Received: September 13, 2024

Dear Mia Brown:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Bradley Q. Quinn -S

Bradley Quinn
Assistant Director
DHT1C: Division of Anesthesia,
Respiratory, and Sleep Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

The following is a list of all reprocessed single use device (SUD) models that are cleared in this submission.

Model Number	Model Name
4000	Reprocessed RD SET Adt Pulse Oximeter Sensor
4001	Reprocessed RD SET Pdt Pulse Oximeter Sensor
4002	Reprocessed RD SET Inf Pulse Oximeter Sensor
4003	Reprocessed RD SET Adt Pulse Oximeter Sensor

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K241758

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)*
Reprocessed RD SET Pulse Oximeter Sensors are indicated for use in continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR) for use with adult, pediatric, and infant patients during both no motion and motion conditions, and for patients who are well or poorly perfused in hospitals and hospital-type facilities.

Reprocessed RD SET Pulse Oximeter Sensors are not intended to be used as the sole basis for making diagnosis or treatment decisions; they are intended to be used in conjunction with additional methods of assessing clinical signs and symptoms

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
K241758

Applicant Name:	Stryker Sustainability Solutions
Contact Person:	Mia Brown Staff Specialist 1810 Drake Drive Tempe, AZ 85283 Phone: 480-343-1855 Email: mia.brown1@stryker.com
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, DQA
Device Class:	Class II
Date Prepared:	10/15/2024
Predicate Device:	Reprocessed RD SET Adt Pulse Oximeter Sensor (K222019) Masimo Rad-97 and Accessories (K180046)
Predicate Product Code:	NLF, DQA
Description	In a clinical setting, a pulse oximeter (POX) 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 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.
Indications for Use:	Reprocessed RD SET Pulse Oximeter Sensors are indicated for use in continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR) for use with adult, pediatric, and infant patients during both no motion and motion conditions, and for patients who are well or poorly perfused in hospitals and hospital-type facilities. Reprocessed RD SET Pulse Oximeter Sensors are not intended to be used as the sole basis for making diagnosis or treatment decisions; they are intended to be used in conjunction with additional methods of assessing clinical signs and symptoms
Summary of Intended Use and Technologies:	The indications for use for the subject device is similar to that of the predicate device with the exception that the proposed devices includes motion conditions. The design of the reprocessed device is the same as the predicate device. The subject device and the predicate device have the same intended use, principle of operation, measurement application sites, performance specifications, environmental and mechanical specifications, and form factor.
Non-Clinical Testing:	Nonclinical tests were not required for this submission, as there were no changes to the subject device compared to that of the predicate device.
Clinical Testing:	After Institutional Review Board Approval, 11 healthy adults volunteer subjects four women and seven men, age range 18-47 years were included in the study that was conducted May 27 - May 28, 2023. Stryker Sustainability Solutions performed the clinical validation testing of the SpO2 performance under motion conditions on healthy, adult volunteers in the range of 70% to

	100% blood-oxygen saturation. The Arms (average root mean square) for SpO2 under motion conditions was found to be 1.84% and 2.33% for non-woven and woven tape, respectively, over the range of 70-100% blood-oxygen saturation. These Arms 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."
Conclusion:	The results of the non-clinical (K222019) and clinical testing from this submission demonstrate that all requirements and performance specifications were satisfied and support the subject device is substantially equivalent to its predicate devices under motion conditions.