July 22, 2020

Surgical Instrument and Savings Inc (dba Medline ReNewal)
℅ Stephanie Mays
Sr. Regulatory Affairs Specialist, Quality Assurance and Regulatory Affairs
Surgical Instrument Service and Savings Inc (dba Medline ReNewal)
1500 NE Hemlock Ave
Redmond, Oregon 97756

Re: K201699
Trade/Device Name: Medline ReNewal Reprocessed Nellcor OxiMax SpO2 Sensor (model: MAXNAR)
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: NLF
Dated: June 19, 2020
Received: June 22, 2020

Dear Stephanie Mays:

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 ENT, 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201699

Device Name
Medline ReNewal Reprocessed Nellcor OxiMax SpO2 Sensor Model MAXNAR

Indications for Use *(Describe)*
The Medline ReNewal Reprocessed Nellcor OxiMax SpO2 Sensor Model MAXNAR is indicated for single patient use when continuous non-invasive arterial oxygen saturation and pulse rate monitoring is required for adult patients as indicated in the sensor directions for use. This device is for prescription use only.

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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K201699 Reprocessed Nellcor OxiMax SpO2 Sensor included in Submission:

OEM Device Model[a]	Device Name	OEM
MAXNAR	Nellcor OxiMax Pulse Oximeter Sensor (Adult SpO2 Sensor > 40 kg; woven bandage)	Nellcor Puritan Bennett
[a] OEM = original equipment manufacturer.		

K201699 Summary

This 510(k) summary of safety and effectiveness information is prepared in accordance with 21 CFR § 807.92.

Submitter/ Owner	Surgical Instrument Service and Savings (dba Medline ReNewal) 1500 NE Hemlock Ave., Redmond, OR 97756	
Prepared by/Contact Name	Stephanie Boyle Mays Senior Regulatory Affairs Specialist, Quality Assurance/Regulatory Affairs P: 541-516-4205 • F: 541-923-3375 • E:smays@medline.com	
Date Prepared	June 19, 2020	
Device Name and Classification	Proprietary/Trade Name:	Medline ReNewal Reprocessed Nellcor OxiMax SpO2 Sensor, model MAXNAR
	Common or usual name	Oximeter, reprocessed
	Regulatory Name/Reference:	Oximeter; 21 CFR § 870.2700
	Regulatory Class:	Class II
	Product Code:	NLF
Predicate Device	510(k) number:	K181738 (March 22, 2019)
	Proprietary/Trade Name:	Medline ReNewal Reprocessed Nellcor OxiMax SpO2 Sensors, models MAXA, MAXAL, MAXP, and MAXI
	Common or usual name	Oximeter, reprocessed
	Regulatory Name/Reference:	Oximeter; 21 CFR § 870.2700
	Regulatory Class:	Class II
	Product Code:	NLF
	Panel:	Cardiovascular/anesthesiology
	Manufacturer:	Surgical Instrument Service and Savings (dba Medline ReNewal) 1500 NE Hemlock Ave., Redmond, OR 97756
Statement of Indications for Use	The Medline ReNewal Reprocessed Nellcor OxiMax SpO2 Sensor Model MAXNAR is indicated for single patient use when continuous non-invasive arterial oxygen saturation and pulse rate monitoring is required for adult patients as indicated in the sensor directions for use. This device is for prescription use only.	
Device Description	The Medline ReNewal Reprocessed Nellcor OxiMax SpO2 Sensor, model MAXNAR is designed for the continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate in conjunction with a Nellcor Pulse Oximeter. The Medline ReNewal Reprocessed Nellcor OxiMax SpO2 Sensor, model MAXNAR, is intended for prescription use with adult patients in hospitals, hospital-type facilities, and intra-hospital transport. The proposed device is not provided sterile.	

Statement of Intended Use	Medline ReNewal Reprocessed Nellcor OxiMax SpO2 Sensor is indicated for the continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate. It is intended for use with adult patients in hospitals, hospital-type facilities and intra-hospital transport. The device is for prescription use only.
Technological (including features, materials and principles of operation)	The technological characteristics and the fundamental scientific technology of the subject device are similar to the predicate devices. The proposed device is a reprocessed Nellcor OxiMax SpO2 Sensor as are the devices within the scope of predicate K181738. The proposed device uses use an adhesive bandage, light source (LEDs), photodetector (Faraday cage/photodiode), cable, and connector in the same manner as the predicate devices. The predicate devices were used to support intended use, technological characteristics, and performance specifications. (Also see comparison of technological features in the Summary Table)

Performance Testing Nonclinical Tests	The functional characteristics of the predicate and proposed devices were examined in K181738 and were evaluated in accordance with *Pulse Oximeters – Premarket Notifications Submissions [510(k)] Guidance for Industry and Food and Drug Administration Staff* (March 4, 2013).Testing included:
	• Biocompatibility: cytotoxicity, sensitization, irritation; acute systemic toxicity
	• Disinfection
	• Shelf Life
	• Electrical
	• Performance testing:
	  • tissue heating
	  • pulse rate accuracy
	  • active element assessment
	  • adhesive peel and
	  • environment (extreme heat and operating conditions)
	• Cleaning:
	  • visual inspection;
	  • cleaning efficacy (residual protein and residual hemoglobin).

Performance Testing Clinical Tests	The purpose of the clinical trial in predicate submission K181738 (which included proposed device Model MAXNAR) was to perform an oxygen saturation (SpO2) accuracy comparison. The study was conducted in accordance with CFR for Non-significant Risk Investigational Studies, following ISO 14155:2011 *Clinical Investigation of medical devices for human subjects – Good clinical practice* as appropriate and the pulse oximeter guidelines of ISO 80601-2-61:2011 *Procedure for invasive laboratory testing on healthy volunteers* applicable sections and *Pulse Oximeters – Premarket Notifications Submissions [510(k)] Guidance for Industry and Food and Drug Administration Staff* (March 4, 2013). After Institutional Review Board Approval, 10 healthy adults volunteer subjects (ages 25 to 36 yr.; weight 105 – 220 lb.; height 60 – 72 in.; BMI of 20.0 – 33.4) were included in the study which was conducted from May 9 to May 10, 2018 to evaluate the

Performance Testing Clinical Tests *(concluded)*	SpO2 accuracy of the proposed devices. The proposed devices achieved an accuracy of 2% for 70% - 100% SpO2. The study concluded that the SpO2 accuracy performance of the proposed devices passed the A_{rms} specification of 3% under steady state and non-motion conditions for the range of 70% to 100%.
Device Model	MAXNAR

Summary Table: Predicate (unmodified) and Proposed (modified) Medline ReNewal Reprocessed Nellcor OxiMax SpO2 sensor comparison.

Device Characteristics	**Predicate**	**Proposed**	**Comparison**
	Medline ReNewal Reprocessed Nellcor OxiMax SpO2 Sensors	**Medline ReNewal Reprocessed Nellcor OxiMax SpO2 Sensor, MAXNAR**	
510(k) Number	K181738	TBD	N/A
Common Name	Oximeter	Oximeter	Same
Regulation No.	870.2700	870.2700	Same
Product Code	NLF	NLF	As stated
Models	MAXA, MAXAL, MAXP, and MAXI	MAXNAR	As stated
Indications for Use	The Medline ReNewal Reprocessed Nellcor OxiMax SpO2 Sensors models MAXA, MAXP and MAXI are indicated for single patient use when continuous non-invasive arterial oxygen saturation and pulse rate monitoring are required for patients in the sizes indicated in the respective sensor directions for use. These devices are for prescription use only.	The Medline ReNewal Reprocessed Nellcor OxiMax SpO2 Sensor model MAXNAR is indicated for single patient use when continuous non-invasive arterial oxygen saturation and pulse rate monitoring is required for adult patients as indicated in the sensor directions for use. This device is for prescription use only.	Same
Intended Use	The reprocessed Nellcor OxiMax SpO2 Sensors are indicated for the continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate. They are intended for use with pediatric and adult patients in hospitals,	The reprocessed Nellcor OxiMax SpO2 Sensor is indicated for the continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate. It is intended for use with adult patients in hospitals, hospital-type	Same

Summary Table (continued)

Device Characteristics	Predicate	Proposed	Comparison
	Medline ReNewal Reprocessed Nellcor OxiMax SpO2 Sensors	**Medline ReNewal Reprocessed Nellcor OxiMax SpO2 Sensor, MAXNAR**	
Intended Use (concluded)	hospital-type facilities, and intra-hospital transport. These devices are for prescription use only.	facilities, and intra-hospital transport. This device is for prescription use only.	Same
Comparison of technological features	The reprocessed Nellcor OxiMax SpO2 Sensors measure functional oxygen saturation non-invasively via a light signal interacting with tissue, by utilizing the time-varying changes in tissue optical properties that occur with pulsatile blood flow. Red and infrared light-emitting diodes (LEDS) are utilized as light sources. A photodiode acting as a photo detector senses the signal strengths of the two wavelengths of light, which vary with the amount of light transmitted through the tissue. The pulse oximeter receives this electrical information from the sensor and processes the information by use of an algorithm to provide real time values of SpO2, pulse rate and pulse amplitude.	The reprocessed Nellcor OxiMax SpO2 Sensor measures functional oxygen saturation non-invasively, via a light signal interacting with tissue, by utilizing the time-varying changes in tissue optical properties that occur with pulsatile blood flow. Red and infrared light-emitting diodes (LEDS) are utilized as light sources. A photodiode acting as a photo detector senses the signal strengths of the two wavelengths of light, which vary with the amount of light transmitted through the tissue. The pulse oximeter receives this electrical information from the sensor and processes the information by use of an algorithm to provide real time values of SpO2, pulse rate and pulse amplitude.	Same
Intended patient population	Adult (MAXA, MAXAL), Pediatric (MAXP), Infant (MAXI)	Adult	Same as Predicate MAXA, MAXAL

Summary Table (continued)

Device Characteristics	Predicate	Proposed	Comparison
	Medline ReNewal Reprocessed Nellcor OxiMax SpO2 Sensors	**Medline ReNewal Reprocessed Nellcor OxiMax SpO2 Sensor, MAXNAR**	
Patient Weight Range	• > 30 kg = adult (MAXA, MAXAL) • 10 - 50 kg = pediatric (MAXP) 3 - 20 kg = infants (MAXI)	• > 40 kg = adult	Same Within weight range of Predicate MAXA, MAXAL
Application site	• Finger = MAXA, MAXL, MAXP • Toe or digit of similar size = MAXI	• Finger	Same as predicate MAXA, MAXAL, MAXP
Single Use	Yes	Yes	Same
Use Environment	Hospitals, hospital-type facilities, and intra-hospital transport	Hospitals, hospital-type facilities, and intra-hospital transport	Same
Measurement Parameter	Oxygen saturation, pulse rate	Oxygen saturation, pulse rate	Same
Monitor system compatibility	Nellcor OxiMax and Nellcor compatible pulse oximeters	Nellcor OxiMax and Nellcor compatible pulse oximeters	Same
Specified SpO2 measurement range	70% - 100% (MAXA, MAXAL, MAXP, MAXI)	70% - 100%	Same
SpO2 accuracy	70% - 100% ± 2 digits in adults (MAXA, MAXAL, MAXP, MAXI)	70% - 100% ± 2 digits in adults	Same
Pulse rate measurement range (bpm)	20 – 250 bpm (MAXA, MAXAL, MAXP, MAXI)	20 – 250 bpm	Same
Pulse rate accuracy (bpm)	20 – 250 ± 3 digits (MAXA, MAXAL, MAXP, MAXI)	20 – 250 ± 3 digits	Same
Temperature Operational/ Storage	Operational = 5°C - 40°C Storage = 20°C - 60°C	Operational = 5°C - 40°C Storage = 20°C - 60°C	Same
Relative humidity	15% - 95% non-condensing	15% - 95% non-condensing	Same

Summary Table (concluded)

Device Characteristics	Predicate Medline ReNewal Reprocessed Nellcor OxiMax SpO2 Sensors	Proposed Medline ReNewal Reprocessed Nellcor OxiMax SpO2 Sensor, MAXNAR	Comparison
Optical design	Transmissive sensor	Transmissive sensor	Same
Housing design	Adhesive bandage	Adhesive bandage	Same
Conclusion	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 Medline ReNewal Reprocessed Nellcor O2 Sensor, Model MAXNAR is substantially equivalent to the predicate device.		

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