July 3, 2019

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

Re: K191018
Trade/Device Name: Medline ReNewal Reprocessed Masimo LNCS Series Adult and Pediatric SpO2 Adhesive Sensors (models LNCS Adtx, LNCS Pdtx, LNCS Adtx-3, and LNCS Pdtx-3)
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: May 7, 2019
Received: May 8, 2019

Dear Stephanie Boyle 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)*
K191018

Device Name
Medline ReNewal Reprocessed Masimo LNCS Series Adult and Pediatric SpO2 Adhesive Sensors

Indications for Use *(Describe)*
The Medline ReNewal Reprocessed Masimo LNCS Adult and Pediatric SpO2 Adhesive Sensors are indicated for single patient use for continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (measured by an SpO2 sensor) for use with adult and pediatric patients during no motion conditions, and for patients who are well 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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K191018 Reprocessed Masimo LNCS Adhesive Sensors included in Submission:

OEM Device Model[a]	Device Name	OEM
LNCS Adtx (part number 1859)	Masimo LNCS Adhesive Sensor (Masimo Adult SpO2 Sensor, >30 kg, 18 inches)	Masimo Corporation
LNCS Adtx-3 (part number 2317)	Masimo LNCS Adhesive Sensor (Masimo Adult SpO2 Sensor, >30 kg, 3 feet)	Masimo Corporation
LNCS Pdtx (part number 1860)	Masimo LNCS Adhesive Sensor (Masimo Pediatric SpO2 Sensor, 10 - 50 kg, 18 inches)	Masimo Corporation
LNCS Pdtx-3 (part number 2318)	Masimo LNCS Adhesive Sensor (Masimo Pediatric SpO2 Sensor, 10 - 50 kg, 3 feet)	Masimo Corporation
[a] OEM = original equipment manufacturer.		

K191018 510(k) Summary

This 510(k) summary of 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	April 12, 2019	
Device Name and Classification	Proprietary/Trade Name:	Medline ReNewal Reprocessed Masimo LNCS Adult and Pediatric SpO2 Adhesive Sensors
	Common or usual name	Oximeter, reprocessed
	Regulatory Name/Reference:	Oximeter; 21 CFR § 870.2700
	Regulatory Class:	Class II
	Product Code:	NLF
	Panel:	Anesthesiology
Predicate Device	510(k) number:	K101896
	Proprietary/Trade Name:	K101896 Masimo LNCS/M-LNCS Oximetry Sensors
	Common or usual name	Oxygen sensor
	Regulatory Name/Reference:	Oximeter; 21 CFR § 870.2700
	Regulatory Class:	Class II
	Product Code:	DQA
	Panel:	Anesthesiology
	Manufacturer:	Masimo Corporation 40 Parker, Irvine, CA 92618
Reference Device	510(k) number:	K181738
	Proprietary/Trade Name:	Medline ReNewal Reprocessed Nellcor OxiMax SpO2 Sensors
	Common or usual name	Oximeter, reprocessed
	Regulatory Name/Reference:	Oximeter; 21 CFR § 870.2700
	Regulatory Class:	Class II
	Product Code:	NLF
	Panel:	Anesthesiology
	Manufacturer:	Medline ReNewal 1500 NE Hemlock Ave., Redmond, OR 97756

Device Description	Medline ReNewal Reprocessed Masimo LNCS Adult and Pediatric SpO2 Adhesive Sensors, models LNCS Adtx, LNCS Pdtx, LNCS Adtx-3, and LNCS Pdtx-3 are designed for the continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate in conjunction with instruments containing Masimo SET oximetry or licensed to use LNCS sensors. The Medline ReNewal Reprocessed Masimo LNCS sensor models LNCS Adtx, LNCS Pdtx, LNCS Adtx-3, and LNCS Pdtx-3 are intended for prescription use with adult and pediatric patients in hospitals, hospital-type facilities, and intra-hospital transport. The proposed device is not provided sterile.
Statement of Intended Use/Indications for Use	The Medline ReNewal Reprocessed Masimo LNCS Adult and Pediatric SpO2 Adhesive Sensors are indicated for single patient use for 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 and pediatric patients during no motion conditions, and for patients who are well perfused in hospitals and hospital-type facilities.
Technological Characteristics	The technological characteristics and the fundamental scientific technology of the subject devices are identical to the predicate devices. The proposed devices are a reprocessed version of the predicate K101896 devices. These devices 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.)
Comparison of Technological Features	

Performance Testing Nonclinical Tests	The functional characteristics of the subject device have been evaluated in accordance with *Pulse Oximeters – Premarket Notifications Submissions [510(k)] Guidance for Industry and Food and Drug Administration Staff* (March 4, 2013) and have been determined to be substantially equivalent to the predicate device based on the following tests:
	• Biocompatibility: cytotoxicity, sensitization, irritation
	• Disinfection
	• Shelf Life
	• Packaging
	• 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 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 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 Models	LNCS Adtx, LNCS Pdtx, LNCS Adtx-3, and LNCS Pdtx-3

Summary continued on next page.

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Summary: **Predicate, reference and Medline ReNewal Reprocessed Masimo LNCS sensor comparison tables.**

Device Characteristics	Predicate	Reference	Proposed	Comparison
	Masimo LNCS Sensors	**Medline ReNewal Reprocessed Nellcor OxiMax SpO2 Sensors**	**Medline ReNewal Reprocessed Masimo LNCS Adult and Pediatric SpO2 Adhesive Sensors**	**Same devices; original and proposed**
510(k) Number	K101896	K181738	TBD	N/A
Common Name	Oximeter	Oximeter	Oximeter	Same
Regulation No.	870.2700	870.2700	870.2700	Same
Product Code	DQA	NLF	NLF	As stated
Models	LNCS/M-LNCS	Nellcor MAXA, MAXA, MAXAL, MAXP, and MAXI	LNCS Adtx, LNCS Pdtx, LNCS Adtx-3, and LNCS Pdtx-3	As stated
Intended Use/ Indications for Use[a]	The LNCS/M-LNCS Sensors are indicated for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate (measured by an SpO2 sensor) for use with adult, pediatric and infant patients during no motion and motion conditions, and for patients who are well or poorly perfused in hospitals, hospital-type facilities, mobile and home environments.	Medline ReNewal 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 infant, pediatric and adult patients in hospitals, hospital-type facilities, and intra-hospital transport. These devices are for prescription use only.	The Medline ReNewal Reprocessed Masimo LNCS Adult and Pediatric SpO2 Adhesive Sensors are indicated for single patient use for 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 and pediatric patients during no motion conditions, and for patients who are well perfused in hospitals and hospital-type facilities	Medline ReNewal will not make claims for infant or neonatal use, for motion or low perfusion performance; or for use in home environment otherwise same as stated

Continued

Summary: **Predicate, reference and Medline ReNewal Reprocessed Masimo LNCS sensor comparison table (*continued*).**

Device Characteristics	Predicate	Reference	Proposed	Comparison
	Masimo LNCS Sensors	**Medline ReNewal Reprocessed Nellcor OxiMax SpO2 Sensors**	**Medline ReNewal Reprocessed Masimo LNCS Adult and Pediatric SpO2 Adhesive Sensors**	
Technological characteristics	The Masimo Pulse Oximeter System 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 tisse. 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 predicate device and the Medline ReNewal reprocessed device contain dual wavelength LED and photodiode. The LED and photodiode are encased in a pad which attach to the patient using adhesive material. The sensors are connected to a cable and they terminate in a pin connector. Biocompatibility and performance/functional testing demonstrate that the devices are equivalent and are safe and effective for their intended use.	The principle of operation of the reprocessed devices is identical to that of the predicates. There are no changes in performance specifications or method of operation. These devices use an adhesive bandage, light source (LEDs), photodetector (Faraday cage/photodiode), cable, and connector in the same manner as the predicate devices.	As stated Medline ReNewal will not make claims for motion or low perfusion performance; otherwise same as written

Summary: **Predicate, reference and Medline ReNewal Reprocessed Masimo LNCS sensor comparison table (*continued*).**

Device Characteristics	Predicate	Reference	Proposed	Comparison
	Masimo LNCS Sensors	**Medline ReNewal Reprocessed Nellcor OxiMax SpO2 Sensors**	**Medline ReNewal Reprocessed Masimo LNCS Adult and Pediatric SpO2 Adhesive Sensors**	
Intended Patient Population	Adult, Pediatric, Infant, Neonatal and Preterm	Adult, Pediatric, Infant	Adult, Pediatric	As stated
Patient Weight Range	• >30 kg = adult (Adtx, Adtx-3) • 10 - 50 kg = pediatric (Pdtx, Pdtx-3) • 3 - 20 kg = infants (Inf, Inf-L, Inf-3) • < 3 kg = infants - > 40 kg = adults (Neo, Neo-L, Neo-3) • <1 kg = preterm (NeoPt, NeoPt-L, NeoPt-3, NeoPt-500)	• >30 kg = adult (MAXA, MAXAL) • 10 - 50 kg = pediatric (MAXP) • 3 - 20 kg = infants (MAXI)	• >30 kg = adult (Adtx, Adtx-3) • 10 - 50 kg = pediatric (Pdtx, Pdtx-3)	Same as shared models
Preferred Application Site	• >30 kg = middle or ring finger of non-dominant hand (adult - Adtx, Adtx-3) • 10 - 50 kg = middle or ring finger of non-dominant hand (pediatric - Pdtx, Pdtx-3) • 3 - 20 kg = great toe (infants - Inf, Inf-L, Inf-3) < 3 kg = foot (infant) - > 40 kg = middle or ring finger or non-dominant hand (adult - Neo, Neo-L, Neo-3) • < 1 kg = foot (preterm - NeoPt. NeoPt-L, NeoPt-3, NeoPt-500)	• Finger = MAXA, MAXL, MAXP • Toe or digit of similar size = MAXI	• >30 kg = middle or ring finger of non-dominant hand (adult) Adtx, Adtx-3) • 10 - 50 kg = middle or ring finger of non-dominant hand (pediatric) Pdtx, Pdtx-3	Same as shared models

Summary: **Predicate, reference and Medline ReNewal Reprocessed Masimo LNCS sensor comparison table. (*continued*).**

Device Characteristics	Predicate	Reference	Proposed	Comparison
	Masimo LNCS Sensors	**Medline ReNewal Reprocessed Nellcor OxiMax SpO2 Sensors**	**Medline ReNewal Reprocessed Masimo LNCS Adult and Pediatric SpO2 Adhesive Sensors**	
Single Use	Yes	Yes	Yes	Same
Use Environment	Hospitals, hospital-type facilities, mobile and home environments	Hospitals, hospital-type facilities, and intra-hospital transport	Hospitals and hospital-type facilities	As stated
Measurement Parameter	Oxygen saturation, pulse rate	Oxygen saturation, pulse rate	Oxygen saturation, pulse rate	Same
Monitor system compatibility	Instruments containing Masimo SET oximetry or licensed to use LNCS sensors and also with Nellcor and Nellcor compatible pulse oximeters	Nellcor OxiMax and Nellcor compatible pulse oximeters	Instruments containing Masimo SET oximetry or licensed to use LNCS sensors	As stated
Specified SpO2 measurement range	70% - 100% for adults/pediatrics/ infants/ neonates	70% - 100% for adults, pediatrics, infants	70% - 100% for adults/pediatrics	Medline ReNewal is same as predicate
SpO2 accuracy	70% - 100% ± 2 digits for adults/pediatrics/ infants and ±3 for neonates	70% - 100% ± 3 digits for adults/pediatrics/ infants	70% - 100% ± 2 digits for adults/pediatrics	Same
Pulse rate measurement range	25 – 240 bpm for adults/pediatrics/ infants/ neonates per Masimo monitor manual	20 – 240 bpm for adults/pediatrics/ infants	25 – 240 bpm adults/pediatrics	Medline ReNewal is same as predicate
Pulse rate accuracy	25 – 240 bpm ± 3 digits for adults/ pediatrics/ infants/ neonates[b]	20 – 250 bpm ± 3 digits for adults/ pediatrics/ infants	25 – 240 bpm ± 3 digits for adults/ pediatrics	Medline ReNewal is same as predicate

Summary: **Predicate, reference and Medline ReNewal Reprocessed Masimo LNCS sensor comparison table. (*concluded)*.**

Device Characteristics	Predicate	Reference	Proposed	Comparison
	Masimo LNCS Sensors	**Medline ReNewal Reprocessed Nellcor OxiMax SpO2 Sensors**	**Medline ReNewal Reprocessed Masimo LNCS Adult and Pediatric SpO2 Adhesive Sensors**	
Temperature Operational/ Storage	Operational = 5°C – 40°C Storage = -40°C - 70°C	Operational = 5°C – 40°C Storage = -20°C - 60°C	Operational = 5°C – 40°C Storage = -40°C - 70°C	Medline ReNewal is same as predicate
Humidity	5% to 95%	15% to 95% non-condensing	5% to 95%	Medline ReNewal is same as predicate
Optical Design	Transmissive sensor	Transmissive sensor	Transmissive sensor	Same
Housing Design	Adhesive bandage	Adhesive bandage	Adhesive bandage	Same

[a] Indications for use/Intended use were the same category in K101896. The K101896 material was obtained from the FDA 510(k) database.
[b] Pulse rate accuracy for the K101896 predicate is in accordance with the Masimo monitor manuals Rad-7 and Rad-8.

Conclusion	Based on a comparison of the intended use/indications for use, technological characteristics, and performance data to the predicate devices, Medline ReNewal Reprocessed Masimo LNCS Sensors Adult and Pediatric SpO2 Adhesive Sensors are substantially equivalent to the predicate device.