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

Re: K181738
Trade/Device Name: Medline ReNewal Reprocessed Nellcor OxiMax S_pO_2 Sensors, models MAXA, MAXAL, MAXP, and MAXI
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: NLF
Dated: February 18, 2019
Received: February 19, 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 D. Courtney -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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)*
K181738

Device Name
Medline ReNewal Reprocessed Nellcor OxiMax SpO2 Sensors Models MAXA, MAXAL, MAXP and MAXI

Indications for Use *(Describe)*
The Medline ReNewal Reprocessed Nellcor OxiMax SpO2 Sensors models MAXA, MAXAL, MAXP, and MAXI are indicated for single patient use when continuous noninvasive 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.

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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K181738 510(k) Summary

This 510(k) summary 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 Regulatory Affairs Specialist, Quality Assurance/Regulatory Affairs P: 541-516-4205 • F: 541-923-3375 • E:smays@medline.com	
Date Prepared	February 18, 2019	
Device Name and Classification	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
Predicate Device	510(k) number:	K052186
	Proprietary/Trade Name:	Nellcor OxiMax Pulse Oximeter Sensors, models MAX-A, MAX-AL, MAX-N, MAX-P, MAX-I and MAX-FAST
	Common or usual name	Oxygen sensor
	Regulatory Name/Reference:	Oximeter; 21 CFR § 870.2700
	Regulatory Class:	Class II
	Product Code:	DQA
	Panel:	Cardiovascular/anesthesiology
	Manufacturer:	Nellcor Puritan Bennett, Inc. 4280 Hacienda Dr., Pleasanton, CA 94588
Reference Device	510(k) number:	K041867
	Proprietary/Trade Name:	Hygia Health Services Reprocessed OxiMax Sensors Model # HHS-MAX-A, HHS-MAX-AL, HHS-MAX-N
	Regulatory Name/Reference:	Oximeter; 21 CFR § 870.2700
	Common or usual name	Oximeter, reprocessed
	Regulatory Class:	II
	Product Code:	NLF
	Panel:	Cardiovascular/anesthesiology
	Manufacturer:	Hygia Health Services, Inc. 434 Industrial Lane, Birmingham, AL 35211

Statement of Indications for Use	The Medline ReNewal Reprocessed Nellcor OxiMax SpO2 Sensors models MAXA, MAXAL, MAXP, and MAXI are indicated for single patient use when continuous noninvasive 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.
Device Description	The Medline ReNewal Reprocessed Nellcor OxiMax SpO2 Sensors, models MAXA, MAXAL, MAXP, and MAXI are 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 Reprocessed Nellcor OxiMax SpO2 Sensors, models MAXA, MAXAL, MAXP, and MAXI are intended for prescription use with adult, pediatric and infant 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 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.
Technology *(including features, materials and principles of operation)*	The technological characteristics and the fundamental scientific technology of the subject devices are identical to the predicate and reference devices. The proposed devices are a reprocessed version of the predicate K052186 device. 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 and reference 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 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; 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 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	MAXA, MAXAL, MAXP, and MAXI

Summary continued on next page.

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Summary Table: Predicate, Reference and Medline ReNewal Reprocessed Covidien Nellcor OxiMax pulse oximeter sensor comparison.

Device Characteristics	Predicate	Reference	Proposed	Comparison
	Covidien Nellcor OxiMax Pulse Oximeter Sensors	**Hygia Health Services Reprocessed OxiMax Sensors**	**Medline ReNewal Reprocessed Nellcor OxiMax SpO2 Sensors**	**Same devices; original and reprocessed**
510(k) Number	K052186	K041867	K181738	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	MAXA, MAXAL, MAXN, MAXP, MAXI and MAXFAST	MAXA, MAXAL, MAXN	MAXA, MAXAL, MAXP, and MAXI	As stated
Indications for use	The Nellcor OxiMax Pulse Oximetry Sensors, models MAX-A, MAX-AL, MAX-N, MAX-P, MAX-I and MAX-FAST are indicated for single patient use when continuous noninvasive arterial oxygen saturation and pulse rate monitoring are required for patients in the sizes indicated in the respective sensor directions for use.	The sensor is indicated for use as a non-invasive method to provide continuous SpO2 monitoring and pulse rate.	The Medline ReNewal Reprocessed Nellcor OxiMax SpO2 Sensors models MAXA, MAXAL, MAXP, and MAXI are indicated for single patient use when continuous noninvasive 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 predicate and proposed devices have the same indications. The predicate and reference devices share the same predicate, K012891.
Intended use	The OxiMax Pulse Oximeter System 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 neonatal, pediatric, and adult patients	None listed	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	Medline Renewal will only reprocess pulse oximeter sensors. Medline ReNewal will not make claims for neonatal use or for motion or low

Summary Table: Predicate, Reference and Medline ReNewal Reprocessed OxiMax comparison (*continued*).

Device Characteristics	Predicate	Reference	Proposed	Comparison
	Covidien Nellcor OxiMax Pulse Oximeter Sensors	**Hygia Health Services Reprocessed OxiMax Sensors**	**Medline ReNewal Reprocessed Nellcor OxiMax SpO2 Sensors**	
Intended use concluded	during both no motion and motion conditions and for patients who are either well or poorly perfused, in hospitals, hospital-type facilities, intra-hospital transport, and home environments. These devices are for prescription only.		patients in hospitals, hospital-type facilities, and intra-hospital transport. These devices are for prescription use only.	perfusion performance; otherwise same as written
Comparison of technological features	The OxiMax 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 tissue. The pulse oximeter receives this electrical information from the	The predicate device and the Hygia reprocessed device contain dual wavelength LED and photodiode. The LED and photodiode are encased in a pad which attached 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 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	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. Medline ReNewal, however, will only reprocess the proposed devices and not any other monitors, components or accessories of the

Summary Table: Predicate, Reference and Medline ReNewal Reprocessed OxiMax comparison (*continued*).

Device Characteristics	Predicate	Reference	Proposed	Comparison
	Covidien Nellcor OxiMax Pulse Oximeter Sensors	**Hygia Health Services Reprocessed OxiMax Sensors**	**Medline ReNewal Reprocessed Nellcor OxiMax SpO2 Sensors**	
Technological features concluded	sensor and processes the information by use of an algorithm to provide real time values of SpO2, pulse rate and pulse amplitude.		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.	system
Intended patient population	Adult, Pediatric, Infant, Neonate	Adult, Pediatric, Infant, Neonate	Adult, Pediatric, Infant	Same as shared models
Patient weight range	• >30 kg = adult (MAXA, MAXAL) • 10 - 50 kg = pediatric (MAXP) • 3 - 20 kg = infants (MAXI) • < 3 kg infants - > 40 kg adults (MAXN) • unknown = MAXFAST	• >30 kg = adult (MAXA, MAXAL) • < 3 kg infants - > 40 kg adults (MAXN)	• >30 kg = adult (MAXA, MAXAL) • 10 - 50 kg = pediatric (MAXP) • 3 - 20 kg = infants (MAXI)	Same as shared models
Application site	• Finger = MAXA, MAXL, MAXP, MAXN (adult) • Toe or digit of similar size = MAXI • Foot = MAXN (neonate) • Forehead = MAXFAST	• Finger = MAXA, MAXL, MAXN (adult) • Foot = MAXN (neonate)	• Finger = MAXA, MAXL, MAXP • Toe or digit of similar size = MAXI	Same as shared models
Single use	Yes	Yes	Yes	Same

Summary Table: Predicate, Reference and Medline ReNewal Reprocessed OxiMax comparison (*continued*).

Device Characteristics	Predicate	Reference	Proposed	Comparison
	Covidien Nellcor OxiMax Pulse Oximeter Sensors	Hygia Health Services Reprocessed OxiMax Sensors	Medline ReNewal Reprocessed Nellcor OxiMax SpO2 Sensors	
Use environment	Hospitals, hospital-type facilities, intra-hospital transport, and home environments	Hospitals, hospital-type facilities, intra-hospital transport, and home environments	Hospital-type facilities, and intra-hospital transport	Same
Measurement parameter	Oxygen saturation, pulse rate	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	Nellcor OxiMax and Nellcor compatible pulse oximeters	Same
Specified SpO2 measurement range	70% - 100% (MAXA, MAXAL, MAXP, MAXI, MAXN)	0 - 100% (MAXA, MAXAL, MAXP, MAXI, MAXN)	70% - 100% (MAXA, MAXAL, MAXP, MAXI)	Medline ReNewal is same as predicate
SpO2 accuracy	70% - 100% ± 2 digits in adults (MAXA, MAXAL, MAXP, MAXI, MAXN) 70% - 100% ± 3 digits in neonates (MAXN)	70% - 100% ± 3 digits (MAXA, MAXAL, MAXP) 70% - 100% ± 3 digits in adults (MAXI, MAXN) 70% - 100% ± 4 digits in neonates (MAXI, MAXN)	70% - 100% ± 2 digits in adults (MAXA, MAXAL, MAXP, MAXI)	Medline ReNewal is same as predicate
Pulse rate measurement range	20 – 250 bpm (MAXA, MAXAL, MAXP, MAXI, MAXN)	30 – 240 bpm (MAXA, MAXAL, MAXP, MAXI, MAXN)	20 – 250 bpm (MAXA, MAXAL, MAXP, MAXI)	Medline ReNewal is same as predicate

continued

Summary Table: Predicate, Reference and Medline ReNewal Reprocessed OxiMax comparison (*concluded*).

Device Characteristics	Predicate	Reference	Proposed	Comparison
	Covidien Nellcor OxiMax Pulse Oximeter Sensors	**Hygia Health Services Reprocessed OxiMax Sensors**	**Medline ReNewal Reprocessed Nellcor OxiMax SpO2 Sensors**	
Pulse rate accuracy (beats per minute)	20 – 250 ± 3 digits (MAXA, MAXAL, MAXP, MAXI, MAXN)	30 to 240 ± 3 digits (MAXA, MAXAL, MAXP, MAXI, MAXN)	20 – 250 bpm ± 3 digits (MAXA, MAXAL, MAXP, MAXI)	Medline ReNewal is same as predicate
Temperature Operational/Storage (°C)	Operational = 5°C – 40°C Storage = -20°C - 60°C	Operational = -2°C - 42°C Storage: -38°C - 49°C	Operational = 5°C – 40°C Storage = -20°C - 60°C	Medline ReNewal is same as predicate
Relative Humidity	15% to 95% non-condensing	15% to 95% non-condensing	15% to 95% non-condensing	Same
Optical Design	Transmissive sensor	Transmissive sensor	Transmissive sensor	Same
Housing design	Adhesive bandage	Adhesive bandage	Adhesive bandage	Same
[a] Intended Use/Indications for Use are the same section in the summary of K052186.				

Conclusion	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 OxiMax SpO2 Sensors are substantially equivalent to the predicate device.