May 6, 2022

Covidien llc
Greeshma Kayala
Regulatory Affairs Manager
6135 Gunbarrel Avenue
Boulder, Colorado 80301

Re: K212555
Trade/Device Name: Nellcor OxySoft Neonatal-Adult SpO2 Sensor, OxySoftN, Nellcor OxySoft Neonatal-Adult SpO2 Sensor, OxySoftNHC
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: April 1, 2022
Received: April 4, 2022

Dear Greeshma Kayala:

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 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)*
K212555

Device Name
Nellcor™ OxySoft™ Neonatal-Adult SpO2 Sensor, OxySoftN/OxySoftNHC

Indications for Use *(Describe)*
The Nellcor™ OxySoftN single patient use sensor is indicated for use with neonatal, infant, pediatric and adult patients 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, mobile emergency medical applications including both ground and air transport and home environments. Transport environments include intra-hospital transport and both ground and air emergency transport: road ambulances and fixed-wing aircraft and helicopters. The Nellcor™ OxySoft SpO2 Sensor works in conjunction with monitoring systems that use OxiMax™ and Nellcor compatible pulse oximetry systems to facilitate spot checking or continuous monitoring of a patient's arterial hemoglobin (SpO2) and pulse rate via topical application of the sensor over a pulsating arteriolar vascular bed, such as a finger, foot or hand. 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.

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510(k) Summary

SUBMITTER INFORMATION

Submitted By:

Covidien, llc
6135 Gunbarrel Avenue
Boulder, CO 80301

Date Prepared: May 2, 2022

Contact Person:

Official Correspondent: Elli Marrs, Regulatory Affairs Specialist

Secondary Correspondent: Greeshma Kayala, Sr. Regulatory Affairs Manager
Phone: (303) 579-1718
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DEVICE NAME

Trade Name:	Nellcor™ OxySoft™ Neonatal-Adult SpO2 Sensor OxySoftN Nellcor™ OxySoft™ Neonatal-Adult SpO2 Sensor OxySoftNHC
Common Name:	Oximeter
Classification Regulation:	21 CFR 870.2700
Classification Name:	Oximeter
Regulatory Class:	Class II
Product Code:	DQA
Review Panel:	Anesthesiology

PREDICATE DEVICE

Predicate Manufacturer:	Covidien
Predicate Trade Name:	Nellcor™ Neonatal-Adult SpO2 Sensor, MAXN
Predicate 510(k):	K012891
Clearance Date:	March 7, 2002

No reference devices were used in this submission.

DEVICE DESCRIPTION

The Nellcor™ OxySoft™ Neonatal/Adult SpO2 Sensor, OxySoftN/ OxySoftNHC monitors the amount of oxygen in the patient's blood (oxygen saturation) or SpO2 and pulse rate after applying the sensor on the finger, foot, or hand. The sensor utilizes a pair of light emitting diodes (LEDs) employing light at two wavelengths, and the time varying absorbance of the

tissue due to the pulsatile blood signal is obtained, amplified and digitized from a photodiode to determine functional arterial oxygen saturation.

A clinician will prescribe the sensor for use as spot check or continuous use in hospitals, hospital-type facilities, intra-hospital transport, mobile emergency medical applications including both ground and air transport and home environments. The OxySoftN/ OxySoftNHC sensor can be used with all Nellcor™ compatible systems.

The sensor consists of a sensor assembly and cable assembly and is provided sterile (EtO) and is meant for single use.

NOTE: The two model numbers represent only one sensor type, OxySoftN. The 'HC' suffix denotes the model number that includes an additional Home Use Guide for the lay user for home use.

INTENDED USE AND INDICATIONS FOR USE

Intended Use:

The Nellcor™ OxySoft™ Neonatal-Adult SpO_2 Sensor, model OxySoftN, is intended for use in non-invasive continuous or spot-check monitoring of functional oxygen saturation of arterial oxygen saturation (SpO_2) and pulse rate for neonates and infants weighing less than 3 kg or adults and pediatrics weighing more than 40 kg.

Indications for Use:

The Nellcor™ OxySoftN single patient use sensor is indicated for use with neonatal, infant, pediatric and adult patients 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, mobile emergency medical applications including both ground and air transport and home environments. Transport environments include intra-hospital transport and both ground and air emergency transport: road ambulances and fixed-wing aircraft and helicopters. The Nellcor™ OxySoft™ SpO2 Sensor works in conjunction with monitoring systems that use OxiMax™ and Nellcor compatible pulse oximetry systems to facilitate spot checking or continuous monitoring of a patient's arterial hemoglobin (SpO2) and pulse rate via topical application of the sensor over a pulsating arteriolar vascular bed, such as a finger, foot or hand. This device is for prescription use only.

CONTRAINDICATIONS

The OxySoftN sensor is contraindicated for use on patients who exhibit allergic reactions to synthetic fabrics or silicone.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Nellcor™ OxySoft™ Neonatal-Adult SpO2 Sensor, models OxySoftN and OxysoftNHC are designed for the same functionality as the predicate device sensors, Nellcor™ Neonatal-Adult SpO2 Sensor, MAXN, measuring functional oxygen saturation.

The following technological characteristics were compared between the subject device and predicate device to demonstrate substantial equivalence in Table 1 below.

Table 1. Comparison of Technological Characteristics

Characteristic	Subject Device Nellcor™ OxySoft™ Neonatal-Adult SpO_2 Sensor, OxySoftN and OxySoftNHC	Predicate Device Nellcor™ Neonatal-Adult SpO_2 Sensor, MAXN (K012891)	Comments
Device	Oximeter	Oximeter	Same
Product Code	DQA	DQA	Same
Device Class	II	II	Same
Indications for Use	The Nellcor™ OxySoftN single patient use sensor is indicated for use with neonatal, infant, pediatric and adult patients 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, mobile emergency medical applications including both ground and air transport and home environments. Transport environments include intra-hospital transport and both ground and air emergency transport: road ambulances and fixed-wing aircraft and helicopters. The Nellcor™ OxySoft SpO2 Sensor works in conjunction with monitoring systems that use OxiMax™ and Nellcor compatible pulse oximetry systems to facilitate spot checking or continuous monitoring of a patient's arterial hemoglobin (SpO2) and pulse rate via topical application of the sensor over a pulsating arteriolar vascular bed, such as a finger, foot or hand. This device is for prescription use only.	The OxiMax™ single patient use sensors (which includes the MaxN) is indicated for use with neonatal, infant, pediatric, and adult patients 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 use only.	Different: Indications for Use were updated to include clarity of systems OxySoftN is compatible with. Additionally environments for use were expanded to include home use environments and mobile emergency medical applications, including both ground and air transport, environments which is supported by compliance to IEC 60601-1-11:2015 and IEC 60601-1-12:2014.

Characteristic	Subject Device Nellcor™ OxySoft™ Neonatal-Adult SpO_2 Sensor, OxySoftN and OxySoftNHC	Predicate Device Nellcor™ Neonatal-Adult SpO_2 Sensor, MAXN (K012891)	Comments
Purpose and Function	Non-invasive continuous or spot-check monitoring of functional oxygen saturation of arterial oxygen saturation (SpO_2) and pulse rate	Non-invasive continuous monitoring of functional oxygen saturation of arterial oxygen saturation (SpO_2) and pulse rate	Same
Target Population	Neonatal, infant, pediatric, and adult patients	Neonatal, infant, pediatric, and adult patients	Same
Intended User	Professionally trained health care providers, patients or a lay operator assisting a patient in a home-care environment	Professionally trained health care providers, patients or a lay operator assisting a patient in a home-care environment	Same
Where Used	In hospitals, hospital-type facilities, intra-hospital transport, mobile emergency medical applications including both ground and air transport and home environments. Transport environments include intra-hospital transport and both ground and air emergency transport: road ambulances and fixed-wing aircraft and helicopters.	In hospitals, hospital-type facilities, intra-hospital transport, and home environments.	Different: Environments for use were expanded to include home use environments and mobile emergency medical applications, including both ground and air transport, environments which is supported by compliance to IEC 60601-1-11:2015 and IEC 60601-1-12:2014.
Energy source	Sensor itself has no energy source. When used with a compatible monitor (powered by battery or AC power source), the monitor powers the sensor.	Sensor itself has no energy source. When used with a compatible monitor (powered by battery or AC power source), the monitor powers the sensor.	Same
Fundamental Technology	Transmittance sensor that measures functional oxygen saturation and pulse rate non-invasively: utilizing spectrophotometry, a pair of light emitting diodes (LEDs) employs light at two	Transmittance sensor that measures functional oxygen saturation and pulse rate non-invasively: utilizing spectrophotometry, a pair of light emitting diodes (LEDs) employs light at two	Same

Characteristic	Subject Device Nellcor™ OxySoft™ Neonatal-Adult SpO_2 Sensor, OxySoftN and OxySoftNHC	Predicate Device Nellcor™ Neonatal-Adult SpO_2 Sensor, MAXN (K012891)	Comments
	wavelengths, and using plethysmography, the time varying absorbance of the tissue due to the pulsatile blood signal is obtained, amplified and digitized from a photodiode to determine functional arterial oxygen saturation.	wavelengths, and using plethysmography, the time varying absorbance of the tissue due to the pulsatile blood signal is obtained, amplified and digitized from a photodiode to determine functional arterial oxygen saturation.	
Performance Standards	EN ISO 80601-2-61 ISO 80601-2-61	EN ISO 80601-2-61	Same
Key Performance Specifications	**Pulse rate accuracy:** +/- 3 BPM RMS **SpO_2 Accuracy (Adult and Neonate with Motion):** 70% to 100% (+/- 3% RMS) **SpO_2 Accuracy (Adult and Neonate):** 70% to 100% (+/- 2% RMS) **SpO_2 Accuracy (Low Saturation):** 60% to 80% (+/- 3% RMS) **SpO_2 Accuracy (Low Perfusion):** 70% to 100% (+/- 2% RMS)	**Pulse rate accuracy:** +/- 3 BPM RMS **SpO_2 Accuracy (Adult and Neonate with Motion):** 70% to 100% (+/- 3% RMS) **SpO_2 Accuracy (Adult and Neonate):** 70% to 100% (+/- 2% RMS) **SpO_2 Accuracy (Low Saturation):** 60% to 80% (+/- 3% RMS) **SpO_2 Accuracy (Low Perfusion):** 70% to 100% (+/- 2% RMS)	Same
External Materials	Polyurethane Silicone Synthetic fabric Aluminum polypropylene Synthetic rubber PVC	Polyethylene Acrylic Woven cotton Polypropylene Rayon elastic PVC	Different: The subject and predicate device have equivalent materials, with the exception of the bandage and adhesive. The subject device was assessed for form, fit and function through a clinical study, MDT20002VALNIC.
Main Safety Standards	IEC 60601-1 IEC 60601-1 2 IEC 60601-1-2 IEC 60601-1-2	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-2 IEC 60601-1-2	Different: Expanded to include IEC 60601-1-11 and IEC

Characteristic	Subject Device Nellcor™ OxySoft™ Neonatal-Adult SpO_2 Sensor, OxySoftN and OxySoftNHC	Predicate Device Nellcor™ Neonatal-Adult SpO_2 Sensor, MAXN (K012891)	Comments
	IEC 60601-1-11 IEC 60601-1-12		60601-1-12 to address emergency and home use environments.

The subject device, the Nellcor™ OxySoft™ Neonatal-Adult SpO2 Sensor, models OxySoftN and OxysoftNHC, has the same principle of operation, intended use, patient population and fundamental technology as the predicate device, Nellcor™ Neonatal-Adult SpO2 Sensor, MAXN.

The differences in technological characteristics do not alter the fundamental performance or the clinical use of the device, therefore, these differences do not raise different questions of safety and effectiveness based on the performance data and clinical studies, summarized below.

PERFORMANCE DATA SUMMARY

The following performance data were provided to support the substantial equivalence determination for the modification being made as part of this submission.

Biocompatibility Testing

The Nellcor™ OxySoft™ Neonatal-Adult SpO2 Sensor, models OxySoftN and OxysoftNHC are classified as surface devices with permanent (>30 days) skin contact. The biocompatibility evaluation was conducted in accordance with International Standard (ISO) 10993-1 “Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process” and FDA Biocompatibility Guidance “Use of International Standard ISO 10993-1, ‘Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.’”

The biocompatibility assessment included the following:

- Cytotoxicity (MEM elution method)
- Sensitization (Guinea pig maximization)
- Intracutaneous reactivity
- Chemical characterization and toxicological risk assessment

Electrical Safety and Electromagnetic Compatibility (EMC)

Electrical safety and EMC testing were conducted on the Nellcor™ OxySoft™ Neonatal-Adult SpO2 Sensor, models OxySoftN and OxysoftNHC. The sensor complies with the IEC 60601-1 standard for safety and the IEC 60601-1-2 standard for EMC.

Non-clinical Performance Testing

Non-clinical testing for the Nellcor™ OxySoft™ Neonatal-Adult SpO2 Sensor, models OxySoftN and OxysoftNHC included the following:

- Mechanical
- Use Life
- Type 1 Light Shunting
- Storage Altitude
- Storage Temperature and Humidity
- Ambient Light
- Ingress Protection
- Shock and Vibration
- Time to Post
- Adhesive Liner Card and Initial Peel Force
- Nellcor Functional Compatibility
- Surface Temperature Rise Measurement System
- Operational Altitude
- Operational Humidity and Temperature
- Transient Temperature and Humidity
- Pulse Rate Motion
- Low Perfusion
- Human Factors

Non-clinical testing was performed to demonstrate that the User Requirements and Product Requirements have been fulfilled. Specifically, testing was completed to demonstrate that the subject device is substantially equivalent to the predicate device and as safe and effective with respect to design characteristics and performance. A Human Factors Validation study was used to evaluate shortening of the subject device cable and confirmed that this design attribute did not contribute to any or existing usability issues. Ingress Protection testing was performed to ensure subject device functions, including the new bandage material, after being subjected to particle IP3X and liquid ingress IPX3 conditioning per IEC 60529. To demonstrate that the new adhesive material of the subject device adds benefit but does not impact clinical use or performance, biocompatibility testing was performed.

Animal Performance Testing

Not applicable. No animal performance testing was required to demonstrate device safety and effectiveness.

Clinical Studies

To support the substantial equivalence of the subject device with the expanded indications for use Nellcor™ OxySoft™ Neonatal-Adult SpO2 Sensor, OxySoftN/ OxySoftNHC, clinical studies were conducted.

MDT20002VALNIC: Performance evaluation of the OxySoftN neonatal sensor in the NICU compared to SaO2

A clinical validation study, Performance Evaluation of the Nellcor™ OxySoft™ Neonatal-Adult SpO2 Sensor, OxySoftN (subject device) in the NICU Compared to SaO2 was performed. Arterial samples were collected on neonates to demonstrate form, fit, and function (clinical performance) of the Nellcor™ OxySoft™ Neonatal-Adult SpO2 Sensor, OxySoftN (subject

device). The standard reference for the SpO2 accuracy as read by pulse oximetry equipment was compared to SaO2 values obtained from CO-oximeter analysis of simultaneously drawn arterial blood. The observed SpO2 accuracy was 2.68% in a study of 27 patients with ages of 1 to 9 days, weight from 640 to 4710 grams, and 64 observations made spanning a range of 82.1% to 99.3% SaO2. There was acceptable evidence to demonstrate safe form and fit of the OxySoftN sensor when applied to 31 patients in the intended neonate population.

MDT20037CYBOXY: Validation of the OxySoftN to Determine the Gentleness on Fragile Skin

A clinical study was performed on healthy elderly subjects (known for having fragile skin) to evaluate evaporative water loss (TEWL), and amount of skin protein disruption between the Nellcor™ OxySoft™ Neonatal-Adult SpO2 Sensor, OxySoftN (subject device) and the Nellcor™ Neonatal-Adult SpO2 Sensor, MAXN (predicate device) to evaluate gentleness of the new adhesive OxySoftN (subject device). The clinical study data demonstrated the adhesive removed significantly less cells than MAXN sensor (predicate device) and caused a minimal increase in TEWL on subjects likely to have fragile skin.

MDT20047OXSNOF: Sensor-Off Validation of the OxySoftN sensor in Healthy Adults

A clinical study, Nellcor™ Sensor-Off Validation of the Nellcor™ OxySoft™ Neonatal-Adult SpO2 Sensor, OxySoftN (subject device) in healthy adults was performed to further ensure the clinical use of the sensor, and validated that the investigational OxySoftN oximetry sensor displayed a “Sensor Off” message within 1 minute after the sensor is removed at least 90% of the time. A sequence of steps for different sensor off configurations was performed per subject. This study was completed to determine whether simulated and real-world situations known to represent challenges to pulse oximetry have an effect on the ability of the “Sensor Off” feature to function according to product design specifications. The study demonstrated the sensor off feature performance with a sample proportion of 0.996 and 95% lower bound for the proportion of success of 0.983. The results demonstrate the device posts a “Sensor Off” message within 1 minute after the sensor is removed at least 90% of the time.

MDT20038CYBADH: Multiple Reposition Peel Adhesion on Human Skin Validation, OxySoftN

The objective of this study was to demonstrate that the Nellcor™ OxySoft™ Neonatal-Adult SpO2 Sensor, OxySoftN (subject device) remains adhered to the skin after the 18th repositioning by measuring peel adhesion as the sensor was serially removed and reapplied to alternating sites on the volar forearm of healthy adults using standardized in-vivo testing procedures. The study concluded that the OxySoftN Sensor can be repositioned and remains adhered to the skin after the 18th repositioning using the above mentioned standardized in-vivo testing procedures.

MDT20028OXYLOV: SpO2 Accuracy Validation of the OxySoftN sensor via Reference CO-Oximetry in Healthy, Well-Perfused Subject

The purpose of this study was to directly compare the Nellcor™ OxySoft™ Neonatal-Adult SpO2 Sensor, OxySoftN (subject device) saturation measurements, during normal to low saturation, to saturation measurements made by a multi-wavelength CO-oximeter, taken from

arterial blood samples from healthy adult subjects. Additionally, prototype pulse oximeter pulse rate measurements were compared to 3-lead ECG pulse rate measurements made via a multi-parameter monitor. Results of this study concluded, when using the N-600x, PM1000N and Oxicable devices, paired with the OxySoftN sensor, during a saturation range of 60-80%, the system demonstrates expected SpO2 accuracy of ±3% Arms. When using the N-600x, PM1000N and Oxicable devices, paired with the OxySoftN sensor during a saturation range of 70% - 100%, the system demonstrates expected SpO2 accuracy of ±2% Arms. During a saturation range of 60% - 100%, the system demonstrates expected PR accuracy of ≤3 BPM.

MDT20006OXYVMT: SpO2 Accuracy Validation of the OxySoft sensor via Reference CO-Oximetry Motion Study

The primary objective of the study is to investigate the performance of the Nellcor™ OxySoft™ Neonatal-Adult SpO2 Sensor, OxySoftN (subject device) for pulse rate and saturation accuracy in a diverse subject population during motion and non-motion conditions and over a specified saturation range. When using the N-600x device, in conjunction with the OxySoftN sensor, during a saturation range of 70% - 100% and motion conditions, the system demonstrates expected SpO2 accuracy of ±3% Arms. When using the N-600x device, in conjunction with the OxySoftN sensor, during a saturation range of 70% - 100% and motion conditions, the system demonstrates expected PR accuracy of ≤5 BPM. When using the N-395 device, in conjunction with the OxySoftN sensor, during a saturation range of 70% - 100% and non-motion conditions, the system demonstrates expected SpO2 accuracy of ±3% Arms. The N-395 device uses a legacy calibration scheme where the calibration curve is stored in the monitor and the appropriate curve to be used is identified by a resistor value in the sensor connector. The RCAL calibration scheme was replaced by the sensor EPROM digital calibration scheme but to ensure efficacy of the legacy N-395 device the RCAL calibration scheme was included in testing.

CONCLUSIONS

The comprehensive verification and validating testing consisting of non-clinical performance testing and clinical validation studies, demonstrate that the Nellcor™ OxySoft™ Neonatal-Adult SpO2 Sensor, OxySoftN/ OxySoftNHC is substantially equivalent to the predicate device with respect to clinical use case, characteristics and performance.