August 28, 2024

OxiWear, Inc.
% Rita King
Chief Executive Officer
MethodSense, Inc.
1 Copley Parkway, Suite 130
Morrisville, North Carolina 27560

Re: K233827
Trade/Device Name: OxiWear
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA, DPZ
Dated: July 26, 2024
Received: July 29, 2024

Dear Rita King:

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.

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

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)*
K233827

Device Name
OxiWear

Indications for Use *(Describe)*
The OxiWear system is indicated for non-invasive, spot-checking and/or continuous data collection of adult (22+) and adolescent (12-21) patients who are well or poorly perfused, during motion and non-motion conditions. It is intended for use in hospitals, medical facilities, home healthcare environments, and mobile environments. The recommended application site is the helix of the ear.

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.

Summary of 510(k)

OxiWear, Inc. K233827

This 510(k) Summary is in conformance with 21CFR 807.92

Submitter: OxiWear Inc.
1111 Arlington Blvd
#305
Arlington, VA 22209
Phone: 571-212-7526

Primary Contact: Rita King, CEO
MethodSense, Inc.
Email: ritaking@methodsense.com
Phone: 919-313-3961
Fax: 919-313-3979

Company Contact: Shavini Fernando
Chief Executive Officer

Date Prepared: **July 26, 2024**

Device Name and Classification

Trade Name: OxiWear
Common Name: Oximeter
Classification: Class II
Regulation Number: 21 CFR Part 870.2700 – Oximeter
Classification Panel: Cardiovascular
Product Code: DQA
Subsequent Product Code: DPZ

Predicate Device:

	Primary Predicate	Reference Device
Trade Name	Models 8100Q2, 8101Q2, and 8102Q2 Reusable, Ear Clip Pulse Oximeter Sensor	The Rad-G Pulse Oximeter and Accessories
Common Name	Pulse Oximeter Sensor	Oximeter
510(k) Submitter / Holder	Nonin Medical, Inc.	Masimo Corporation
510(k) Number	K160865	K201770
Regulation Number	21 CFR 870.2700	21 CFR 870.2700
Classification Panel	Cardiovascular	Cardiovascular
Product Code	DQA, DPZ	DQA, DPZ, BZQ

Device Description and Intended Use
The OxiWear System is an ear pulse oximeter that non-invasively measures and displays patient blood oxygen saturation (SpO2) and Pulse Rate for spot-checking and/or continuous data collection. The OxiWear System is intended to be used with well or poorly perfused patients of all skin types in both motion and no motion conditions. The system is intended for use in clinical and home environments for adult (22+) and adolescent (12-21) patients of all skin types who are well or poorly perfused, and can safely wear the oximeter device on the helix of the ear. The OxiWear System can be used with patients that are in both motion and stationary conditions.

The OxiWear System contains the OxiWear Charger, OxiWear Wearable, and the OxiWear Mobile Application. The OxiWear Wearable is a wireless, reusable, non-invasive ear pulse oximeter that is intended to measure SpO2 and Pulse Rate based on the amount of transmitted, reflected, and scattered light through the ear. The OxiWear Wearable is powered by an internal rechargeable lithium ion battery, and attaches directly to the helix of the ear. The OxiWear Wearable is intended to be recharged by the OxiWear Charger, which is a rechargeable portable charger.

The OxiWear Wearable is designed to be used with the OxiWear Mobile Application which receives data from the OxiWear Wearable via Bluetooth connection to the user's smart phone. The OxiWear Mobile Application acts as a historical trending, live data monitoring, and text alert application. The Mobile Application is intended to be used alongside the OxiWear Wearable during daily use, as well as a data repository to refer back to previous reports containing information about the patient, such as SpO2 levels, pulse rate, patient contacts, and more, to present to a physician or caregiver for review.

Indications for Use
The OxiWear system is indicated for non-invasive, spot-checking and/or continuous data collection of adult (22+) and adolescent (12-21) patients who are well or poorly perfused, during motion and non-motion conditions. It is intended for use in hospitals, medical facilities, home healthcare environments, and mobile environments. The recommended application site is the helix of the ear.

Risk Analysis Method
The OxiWear system was assessed to determine risks to health associated with the use of the device. Risks related to safety and performance were considered. A risk analysis was conducted in accordance with ISO 14971:2019, Medical devices – Application of risk management to medical devices.

Substantial Equivalence

The table below provides a detailed comparison of OxiWear to the predicate device.

Characteristic	Subject Device OxiWear	Predicate Device Models 8100Q2, 8101Q2, and 8102Q2 Reusable, Ear Clip Pulse Oximeter Sensor (K160865)	Reference Device Rad-G Pulse Oximeter and Accessories (K201770)	Comparison
Intended Use				
Intended Use	OxiWear is intended for non-invasive spot-checking and/or continuous data collection of patients.	Models 8100Q2, 8101Q2, and 8102Q2 Reusable, Ear Clip Pulse Oximeter Sensor is intended for non-invasive, spot-checking and/or continuous monitoring of patients.	The Rad-G Pulse Oximeter and Accessories are intended for the non-invasive spot-checking or continuous monitoring of patients.	Identical as it relates to spot-checking and continuous data collection.
Indications for Use				
Indications for Use	OxiWear is indicated for non-invasive spot-checking and/or continuous data collection of adult (22+) and adolescent (12-21) patients who are well or poorly perfused, during motion and non-motion conditions. It is intended for use in hospitals, medical facilities, home healthcare environments, and mobile environments. The recommended application site is the helix of the ear.	Models 8100Q2, 8101Q2, and 8102Q2 Reusable, Ear Clip Pulse Oximeter Sensor is indicated for non-invasive, spot-checking and/or continuous monitoring of adult and pediatric patients (> 40 kg / 88 lb) who are well or poorly perfused, during non-motion conditions. It is intended for use in hospitals, medical facilities, Emergency Medical Service (EMS) environments, home healthcare environments, and mobile environments. The recommended application site is the earlobe.	The Rad-G Pulse Oximeter and Accessories are intended for the non-invasive spot-checking or continuous monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2), Pulse Rate (PR), and Pleth Respiration Rate (RRp). The Rad-G Pulse Oximeter and Accessories are indicated for noninvasive spot-checking or continuous monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and	Different – This difference does not change the intended use of the device as it relates to the spot-checking and continuous data collection.

Characteristic	Subject Device OxiWear	Predicate Device Models 8100Q2, 8101Q2, and 8102Q2 Reusable, Ear Clip Pulse Oximeter Sensor (K160865)	Reference Device Rad-G Pulse Oximeter and Accessories (K201770)	Comparison
			Pulse Rate (PR) of adult, pediatric, infant, and neonate patients during both no motion and motion conditions, and for patients who are well or poorly perfused in hospitals, hospital-type facilities, transport, and home environments. The Rad-G Pulse Oximeter and Accessories are indicated for the spot-checking or continuous monitoring of Respiration Rate from the photoplethysmogram (RRp) of adult and pediatric patients during no motion conditions in hospitals, hospital-type facilities, transport, and home environments.	
Regulation and Product Code	21 CFR 870.2700 DQA, DPZ	21 CFR 870.2700 DQA, DPZ	21 CFR 870.2700 DQA, DPZ, BZQ	Identical to the predicate device.

Characteristic	Subject Device OxiWear	Predicate Device Models 8100Q2, 8101Q2, and 8102Q2 Reusable, Ear Clip Pulse Oximeter Sensor (K160865)	Reference Device Rad-G Pulse Oximeter and Accessories (K201770)	Comparison
Environment of Use	No motion and motion conditions in hospitals, hospital-type facilities, home healthcare environments, and mobile environments.	Non-motion conditions in hospitals, hospital-type facilities, Emergency Medical Service (EMS) environments, home healthcare environments, and mobile environments.	No motion and motion conditions in hospitals, hospital-type facilities, transport, and home environments.	Equivalent to the combination of the predicate and reference devices. The only difference being that the predicate also includes Emergency Medical Service environments whereas the subject device does not.
Patient Population	Adult (22+) and adolescent (12-21) patients.	Adult and pediatric patients (> 40 kg / 88 lb)	Adult, pediatric, infant, and neonate patients.	Different – This difference in patient population does not change the intended use of the device.
Application Site	Helix of the ear	Earlobe	Fingertip	Different – This difference in application site does not change the intended use of the device.
Display				
Display Type	LCD Touchscreen	LED	LCD Touchscreen	Identical to the reference device.
Notifications				

Characteristic	Subject Device OxiWear	Predicate Device Models 8100Q2, 8101Q2, and 8102Q2 Reusable, Ear Clip Pulse Oximeter Sensor (K160865)	Reference Device Rad-G Pulse Oximeter and Accessories (K201770)	Comparison
Type of Notification	Haptic Notifications	Visual, Audible Alarms	Visual, Audible Alarms	Different – This difference does not change the intended use of the device as it relates to spot-checking and continuous data collection. Continuous monitoring is a more focused use with a higher risk profile.
Technological Characteristics				
Measured Parameters	SpO2, PR	SpO2, PR	SpO2, PR, RRp	Identical to the predicate device.
Materials	SH516U (SHORE 60A) [Silicone] MasterSil 151MED QUART KIT [Silicone] SH0130U SILICONE (SHORE 30A) AKULON CARE K1U (PA6) [Polyamide]	Specific materials unknown; Biocompatible per ISO 10993-1	Specific materials unknown; Biocompatible per ISO 10993-1	Different – This difference does not change the intended use of the device.
Sensor Type	Red and Infrared LEDs	Red and Infrared LEDs	Red and Infrared LEDs	Identical to the predicate device.

Characteristic	Subject Device OxiWear	Predicate Device Models 8100Q2, 8101Q2, and 8102Q2 Reusable, Ear Clip Pulse Oximeter Sensor (K160865)	Reference Device Rad-G Pulse Oximeter and Accessories (K201770)	Comparison
Principle of Operation	The pulse oximeter determines functional oxygen saturation of arterial hemoglobin (SpO2) by measuring the absorption of red and infrared light passing through perfused tissue. Changes in the absorption caused by the pulsation of blood in the vascular bed are used to determine oxygen saturation and pulse rate.	The pulse oximeter determines functional oxygen saturation of arterial hemoglobin (SpO2) by measuring the absorption of red and infrared light passing through perfused tissue. Changes in the absorption caused by the pulsation of blood in the vascular bed are used to determine oxygen saturation and pulse rate.	The pulse oximeter determines functional oxygen saturation of arterial hemoglobin (SpO2) by measuring the absorption of red and infrared light passing through perfused tissue. Changes in the absorption caused by the pulsation of blood in the vascular bed are used to determine oxygen saturation and pulse rate.	Identical to the predicate device.
Performance Specification				
SpO2 Measurement Range	70-100%	70-100%	70-100%	Identical to the predicate device.
SpO2, no motion	± 3.5% (A_{RMS})	± 3% (A_{RMS})	Adults/Pediatrics/Infants: ± 2% (A_{RMS}) Neonates: ± 3% (A_{RMS})	Different – This difference does not change the intended use of the device.
SpO2, motion	± 3.5% (A_{RMS})	N/A	± 3% (A_{RMS})	Different – This difference does not change the intended use of the device.

Characteristic	Subject Device OxiWear	Predicate Device Models 8100Q2, 8101Q2, and 8102Q2 Reusable, Ear Clip Pulse Oximeter Sensor (K160865)	Reference Device Rad-G Pulse Oximeter and Accessories (K201770)	Comparison
SpO2, low perfusion	± 3.5% (A_{RMS})	± 2% (A_{RMS})	Adults/Pediatrics/Infants: ± 2% (A_{RMS}) Neonates: ± 3% (A_{RMS})	Different – This difference does not change the intended use of the device.
Pulse Rate Measurement Range	20-240 BPM	25-240 BPM	25-240 BPM	Different - This difference does not change the intended use of the device.
Pulse Rate, no motion	± 3 BPM (A_{RMS})	± 3 BPM (A_{RMS})	± 3 BPM (A_{RMS})	Identical to the predicate device.
Pulse Rate, motion	± 5 BPM (A_{RMS})	N/A	± 5 BPM (A_{RMS})	Identical to the reference device.
Pulse Rate, low perfusion	± 3 BPM (A_{RMS})	± 3 BPM (A_{RMS})	± 3 BPM (A_{RMS})	Identical to the predicate device.
Environmental				
Operating Temperature	0 to 40 ºC (32 to 104 ºF)	-20 to 50 ºC (-4 to 122 ºF)	0 to 40 ºC (32 to 104 ºF)	Identical to the reference device.
Storage Temperature	-20 to 60 ºC (-4 to 140 ºF)	-40 to 70 ºC (-40 to 158 ºF)	-20 to 60 ºC (-4 to 140 ºF)	Equivalent to the reference device.

Characteristic	Subject Device OxiWear	Predicate Device Models 8100Q2, 8101Q2, and 8102Q2 Reusable, Ear Clip Pulse Oximeter Sensor (K160865)	Reference Device Rad-G Pulse Oximeter and Accessories (K201770)	Comparison
Operating / Storage Humidity	0% to 90% RH, non-condensing	10% to 95% RH, non-condensing	10% to 95% RH, non-condensing	Different – This difference does not change the intended use of the device.
Operating Atmospheric Pressure	700 mbar to 1,060 mbar (700 hPa to 1060 hPa)	≤ 4053 mbar (4053 hPa)	540 mbar to 1,060 mbar (540 hPA to 1060 hPa)	Different – This difference does not change the intended use of the device.
Mechanical				
Instrument Dimensions	18.9 mm width x 28.1 mm height x 27.3 mm depth	219 mm width x 92 mm height x 142 mm depth	7.8 x 2.9 x 1 inch (198 x 74 x 25 mm)	Different – This difference does not change the intended use of the device.
Instrument Weight	~ 50 g (0.05 kg)	900 g (0.9 kg)	270 g (0.27 kg)	Different – This difference does not change the intended use of the device.
Electrical				

Characteristic	Subject Device OxiWear	Predicate Device Models 8100Q2, 8101Q2, and 8102Q2 Reusable, Ear Clip Pulse Oximeter Sensor (K160865)	Reference Device Rad-G Pulse Oximeter and Accessories (K201770)	Comparison
AC Power	Wearable: N/A Charger: 100-240 VAC, 50-60 Hz, 0.6A Note: Input voltage is only applicable while charging. The device is not operational while charging.	100-240 VAC, 50-60 Hz	100-240 VAC, 50-60 Hz, 0.6A	Different – This difference does not change the intended use of the device.
Battery Power	Internally rechargeable lithium ion battery	Internally rechargeable NiMH battery	Internally rechargeable lithium ion battery	Identical to the reference device.
I/O Interface	Wearable Bluetooth: 2402MHz-2480MHz Mobile Application Wi-Fi via smart device	Hirose connector	Wi-Fi, Bluetooth	Equivalent to the reference device.
Mode of Operation				
Mode of Operation	Spot-Checking and Continuous Data collection	Spot-Checking and Continuous Data collection	Spot-Checking and Continuous Data collection	Identical to the predicate device.

Characteristic	Subject Device OxiWear	Predicate Device Models 8100Q2, 8101Q2, and 8102Q2 Reusable, Ear Clip Pulse Oximeter Sensor (K160865)	Reference Device Rad-G Pulse Oximeter and Accessories (K201770)	Comparison
Testing				
Electrical Safety	IEC 60601-1	IEC 60601-1	IEC 60601-1	Identical to the reference device.
Temperature and Humidity	IEC 60601-1	IEC 60601-1 EN 1789	IEC 60601-1	Identical to the reference device.
Atmospheric Pressure (Altitude)	IEC 60601-1	IEC 60601-1	IEC 60601-1	Identical to the reference device.
Electromagnetic Immunity and Emissions	IEC 60601-1-2	IEC 60601-1-2	IEC 60601-1-2	Identical to the reference device.
Performance	ISO 80601-2-61 IEC 60601-1 IEC 60601-1-6 IEC 62304	ISO 80601-2-61 IEC 60601-1 IEC 60601-1-6 IEC 60601-1-12 IEC 62304	ISO 80601-2-61 IEC 60601-1 IEC 60601-1-6 IEC 62304	Equivalent to the reference device.

Characteristic	Subject Device OxiWear	Predicate Device Models 8100Q2, 8101Q2, and 8102Q2 Reusable, Ear Clip Pulse Oximeter Sensor (K160865)	Reference Device Rad-G Pulse Oximeter and Accessories (K201770)	Comparison
Ingress Protection	IEC 60601-1-11 ISO 80601-2-61	ISO 80601-2-61	Ingress Protection Testing was performed.	Equivalent to the predicate device.
Mechanical Durability	IEC 60601-1 ISO 80601-2-61	IEC 60601-1 ISO 80601-2-61	Mechanical Durability Testing was performed.	Equivalent to the predicate device.
Usability	Human Factors / Usability Testing was performed.	Human Factors / Usability Testing was performed.	Human Factors / Usability Testing was performed.	Equivalent to the predicate device.
Biocompatibility	ISO 10993-1 ISO 10993-5 ISO 10993-10 ISO 10993-21	ISO 10993-1 ISO 10993-5 ISO 10993-10	ISO 10993-1 ISO 10993-5 ISO 10993-10	Equivalent to the predicate device. Note that since the clearance of the predicate and reference devices, ISO 10993-10 (sensitivity and irritation) was split into ISO 10993-10 sensitization and ISO 10993-21 irritation.

Characteristic	Subject Device OxiWear	Predicate Device Models 8100Q2, 8101Q2, and 8102Q2 Reusable, Ear Clip Pulse Oximeter Sensor (K160865)	Reference Device Rad-G Pulse Oximeter and Accessories (K201770)	Comparison
Clinical Testing	SpO2 Accuracy – ISO 80601-2-61 SpO2 and Pulse Rate Low Perfusion – ISO 80601-2-61	SpO2 Accuracy – ISO 80601-2-61 SpO2 and Pulse Rate Low Perfusion – ISO 80601-2-61	SpO2 Accuracy – ISO 80601-2-61 SpO2 and Pulse Rate Low Perfusion – ISO 80601-2-61	Equivalent to the predicate device.

Summary of Non-Clinical Testing
The OxiWear system has been evaluated and verified to comply with recognized standards through verification and validation testing. The following testing was performed:

- Biocompatibility evaluation and testing was performed for materials of interest per FDA Guidance “Use of International Standard ISO 10993-1, ‘Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process’” (September, 2023).

- Installation / Operational Performance Qualifications for mobile application.

- Operational performance Qualifications for OxiWear system.

- OxiWear was tested and found to be compliant with the following standards for electrical safety an EMC: IEC 60601-1 Medical Electrical Equipment – Part 1: General Requirements For Basic Safety and Essential Performance and IEC 60601-1-2 Medical Electrical Equipment – Part 1-2: General Requirements For Basic Safety And Essential Performance – Collateral Standard: Electromagnetic Compatibility – Requirements and Tasks.

- Bench Testing was completed for the OxiWear system to confirm the performance of the Wearable and the Charging Case.

- Low perfusion testing was performed wherein low perfusion conditions were simulated using a functional tester. Testing demonstrated that the OxiWear device has a level of SpO2 and Pulse Rate accuracy, under conditions of low perfusion, comparable to an industry standard pulse oximeter.

- No motion pulse rate testing was performed utilizing a simulator. Testing demonstrated that the OxiWear device has a level of no motion pulse rate accuracy comparable to an industry standard pulse oximeter.

- Human Factors and Usability Testing was performed.

- Software verification and validation was performed in accordance with IEC 62304 Medical Device Software – Software Lifecycle Processes

- Front end and back end penetration testing was performed by third party testing laboratories.

Summary of Clinical Testing

OxiWear further evaluated the performance of the OxiWear device through clinical testing performed to confirm that the SpO_2 measurements read by the device are comparable to an industry standard pulse oximeter. No motion SpO2 validation under normal perfusion conditions was conducted under controlled laboratory conditions evaluating the OxiWear system against a cooximeter. Motion SpO2 testing was conducted in subjects wearing the OxiWear device while on a treadmill and evaluating the OxiWear device against a reference pulse oximeter.

Motion testing was also performed for Pulse Rate wherein subjects wore the OxiWear device while on a treadmill and were evaluated against a reference pulse oximeter.

Results from this clinical testing demonstrate that OxiWear has a level of accuracy comparable to an industry standard pulse oximeter.

Substantial Equivalence Conclusions

The intended use of OxiWear is identical to that of the predicate device (K160865) as it relates to both devices are extravascular devices intended for spot- checking and continuous data collection of patient health information. The technological characteristics demonstrate that OxiWear is equivalent to the predicate device (K160865) and reference device (K201770), and testing has demonstrated that OxiWear is substantially equivalent to the predicate device (K160865) and has confirmed that the OxiWear device will be as safe and effective as the predicate device (K160865).

Conclusion

The 510(k) Pre-market Notification for the OxiWear contains adequate information and data to determine that OxiWear is as safe and effective as the legally marketed predicate device(s).