December 5, 2021

Covidien, LLC
Megan Elliott
Sr. Regulatory Affairs Specialist
6135 Gunbarrel Avenue
Boulder, Colorado 80301

Re: K211561
Trade/Device Name: INVOS™ PM7100 Patient Monitor, INVOS™ Pediatric rSO2 Sensor, INVOS™ Infant Regional Saturation Sensor
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: MUD, QEM
Dated: November 4, 2021
Received: November 5, 2021

Dear Megan Elliott:

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,

Jay Gupta
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic Devices
OHT5: Office of Neurological
and Physical Medicine 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)*
K211561

Device Name
INVOS™ PM7100 Patient Monitor
INVOS™ Pediatric rSO2 Sensor
INVOS™ Infant Regional Saturation Sensor

Indications for Use *(Describe)*

The INVOS™ Patient Monitor, model PM7100, is a noninvasive cerebral/somatic oximetry system intended for use as an adjunct monitor of regional hemoglobin oxygen saturation of blood in the brain or in other tissue beneath the sensor. It is intended for use on individuals > 2.5 kg at risk for reduced-flow or no-flow ischemic states. For patients ≤ 2.5kg, the INVOS™ Patient Monitor, model PM7100 is only intended for adjunct trend monitoring of regional hemoglobin oxygen saturation of blood tissue beneath the sensor.

It is also intended for use as an adjunct trend monitor of regional hemoglobin oxygen saturation of blood tissue beneath the sensor in any individual.

The INVOS™ Pediatric rSO2 sensor is indicated for single patient use when cerebral/somatic monitoring of site-specific regional oxygen saturation (rSO2) is required in patients weighing greater than 4 kg and less than 40 kilograms. This sensor is only intended to be used with INVOS™ PM7100 system with INVOS™ Near Infrared Spectroscopy (NIRS) technology. For additional information regarding setup and use of the INVOS™ PM7100 System including indications for use, contraindications, warnings and cautions, consult the Monitoring System Operator's Manual.

The INVOS™ OxyAlert NIRSensor disposable sensor Model IS is indicated for single patient use when cerebral/somatic monitoring of site-specific regional oxygen saturation (rSO2) is required in patients weighing > 2.5 kilograms and < 40 kilograms or for trend monitoring of rSO2 of blood tissue beneath the sensor in any individual < 40kg. This sensor is only intended to be used with INVOS™ Near Infrared Spectroscopy (NIRS) technology including monitoring systems and devices integrated with INVOS™ NIRS technology. For additional information regarding setup and use of the INVOS™ System including indications for use, contraindications, warnings and cautions, consult the Monitoring System Operator's Manual.

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.

510(k) SUMMARY

SUBMITTER INFORMATION:

Submitted By:	Covidien llc 6135 Gunbarrel Avenue Boulder, CO 80301
Contact:	Megan Elliott Senior Regulatory Affairs Specialist
Phone:	(720) 402-1643
Fax:	N/A
Date of Preparation:	December 3rd, 2021

DEVICE NAME:

Trade Name(s):	INVOS™ PM7100 Patient Monitor INVOS™ Pediatric rSO_2 Sensor INVOS™ Infant Regional Saturation Sensor (also referred to as OxyAlert NIRSensor)
Common/Usual Name:	Cerebral Somatic Tissue Oximeter
Classification:	Class II
Classification Name:	Oximeter
CFR Reference:	21 CFR 870.2700
Product Code:	MUD and QEM

PRIMARY PREDICATE DEVICE:

Manufacturer:	Covidien llc
Device Name:	INVOS™ Cerebral/Somatic Oximeter System, Model 5100C
510(k) Number:	K082327
Clearance Date:	April 3, 2009

ADDITIONAL PREDICATE DEVICE:

Manufacturer:	Covidien llc
Device Name:	INVOS™ PM7100 Patient Monitor
510(k) Number:	K182868
Clearance Date:	January 8, 2019

PEDIATRIC SENSOR PREDICATE DEVICE:

ADDITIONAL PREDICATE DEVICE:

Manufacturer:	Covidien llc
Device Name:	INVOS™ Pediatric rSO_2 Sensor SPFB
510(k) Number:	K082327
Clearance Date:	April 3, 2009

INFANT SENSOR PREDICATE DEVICES:

PRIMARY PREDICATE DEVICE:

Manufacturer:	Covidien llc
Device Name:	OxyAlert Infant/Neonatal Somatic NIR Sensor Model IS-S
510(k) Number:	K091224
Clearance Date:	July 9, 2009

ADDITIONAL PREDICATE DEVICE:

Manufacturer:	Covidien llc
Device Name:	OxyAlert Infant/Neonatal Cerebral NIR Sensor Model IS-C
510(k) Number:	K091224
Clearance Date:	July 9, 2009

DEVICE DESCRIPTION:

The INVOS™ PM7100 Patient Monitor is a cerebral/somatic tissue oximeter intended for use as an adjunct trend monitor of regional hemoglobin and oxygen saturation monitoring. The monitor utilizes a near infrared diffuse reflectance spectroscopy system employing near infrared light at four wavelengths for the adult and pediatric system configurations. One pair of wavelengths is used to estimate the percentage of hemoglobin saturated with oxygen in tissue beneath the sensor; another pair of wavelengths is used for the sensor on/off detection algorithm. The infant system configuration currently only employs the two wavelengths needed to estimate regional oxygenated hemoglobin.

The subject device is non-sterile and consists of a multi-channel touch screen display, preamplifier, cables, and three single use sensor types for use in the adult (PMSENS71-A; cleared in K182868), pediatric (PMSENS71-P; new to subject device), and infant (IS; new to subject device) populations.

The subject device utilizes up to four detachable sensors to collect signals, and up to two preamplifiers receive signals from the sensors, digitize the signals, process the data and then periodically estimate the rSO_2 at each sensor site. The preamplifiers then transmit the measured and calculated parameter data to the monitor where the information is displayed. The oximeter is powered primarily by AC power at 100 VAC to 240 VAC ±10% and is equipped with an internal rechargeable lithium-ion battery for intra hospital transport

and back-up purposes. The INVOS™ PM7100 Patient Monitor is intended for use in hospitals, and is not intended for home use or out-of-hospital transport.

The PM7100 Monitor configures the PMPAMP71 preamplifier modules for monitoring operations and allows the user to configure sensor placement assignments on a patient's body as well as establish baseline rSO_2 values. Device features include a user configurable rSO_2 baseline, alarms, signal strength indicator and area under the curve thresholds. The monitor measures and displays an rSO_2 trend line in a graph for the estimated regional oxygen saturation value unique to the specific area under each sensor, the baseline rSO_2 value, the current estimated rSO_2 trend accuracy value and percent change from patient rSO_2 baseline. The PM7100 Monitor also displays alarm information and indicates connected sensor type. The Monitor is equipped with technical (system status) and physiological (patient status) alarms. Alarm conditions are detected via the sensor, the physiological and technical information are then processed in the preamplifier/processor, which then communicates this information to the monitor. The monitor then provides a visual and audio alarm notification. The device permits the user to silence alarms, mark events, and manage case history data.

The PMPAMP71 preamplifier interfaces with the PM7100 monitor via a cable for communications and power, and with one or two sensors via reusable sensor cables to receive optical signals. The optical signal flows from the sensor into the PMPAMP71 which in turn generates saturation information (rSO_2) for tissue under the sensor that is communicated to the PM7100 monitor.

The INVOS™ Adult SpO_2 Sensor, PMSENS71-A, is a non-sterile, non-invasive, disposable sensor intended for application on cerebral and somatic sites. The PMSENS71-A was designed for use with the INVOS™ PM7100 and 5100C cerebral/somatic monitoring systems for monitoring of site-specific regional oxygen saturation (rSO_2) in adult patients weighing >40 kilograms. There have been no significant changes to this sensor since clearance under K182868.

The INVOS™ Pediatric rSO_2 Sensor, PMSENS71-P, is a new non-sterile, non-invasive, disposable sensor intended for application on cerebral and somatic sites in pediatric patients greater than 4 kg and less than 40 kilograms. The PMSENS71-P was designed to support the existing two wavelength rSO_2 algorithm along with a new two wavelength sensor on/off detection algorithm. Accordingly, the PMSENS71-P sensor is designed to emit and collect sensor data with a total of four wavelengths.

The INVOS™ Infant Regional Saturation Sensor, model IS, is a non-sterile, non-invasive, disposable sensor intended for application on cerebral and somatic sites in the infant and neonate patient population. The IS sensor configuration currently only employs the two wavelength rSO_2 algorithm. Accordingly, the IS sensor is designed to emit and collect sensor data with a total of two wavelengths. The INVOS™ Reusable Infant Sensor Adapter Cable (PMAC71RIC) is a new non-sterile, non-invasive reusable cable intended for adapting the infant sensor connection to the PM7100 preamplifier.

The INVOS™ Docking Station connects to the INVOS™ PM7100 Patient Monitor and is designed with a mounting surface on the back of the docking station which can connect to the Patient Monitor Stand or any other compatible mounting service. The docking station is equipped with inputs for AC power, USB, serial port and VGA port. The
docking station also facilitates recharging of the back-up battery. There have been no significant changes to the docking station since clearance in K182868.

The INVOS™ Patient Monitor Stand is an accessory that connects to the INVOS™ Docking Station. The monitor stand has not changed since clearance in K182868.

ACCESSORIES:

INVOS™ Adult rSO_2 Sensor, PM7100 and 5100C	PMSENS71-A
INVOS™ Pediatric rSO_2 Sensor, PM700	PMSENS71-P
INVOS™ Infant Regional Saturation Sensor	IS
INVOS™ Preamplifier	PMPAMP71
INVOS™ Reusable Sensor Cable for PM7100	PMAC71RSC
INVOS™ Reusable Infant Sensor Adapter Cable	PMAC71RIC
INVOS™ Docking Station, PM7100	PMAC71DOC
INVOS™ Patient Monitor Stand, PM7100	PMAC71STAND
INVOS™ Reusable Sensor Cable for 5100C, Channel 1	PMAC71RSC-L-CH1
INVOS™ Reusable Sensor Cable for 5100C, Channel 2	PMAC71RSC-L-CH2
INVOS™ Reusable Sensor Cable for 5100C, Channel 3	PMAC71RSC-L-CH3
INVOS™ Reusable Sensor Cable for 5100C, Channel 4	PMAC71RSC-L-CH4

INDICATIONS FOR USE:

The INVOS™ Patient Monitor, model PM7100, is a noninvasive cerebral/somatic oximetry system intended for use as an adjunct monitor of regional hemoglobin oxygen saturation of blood in the brain or in other tissue beneath the sensor. It is intended for use on individuals > 2.5 kg at risk for reduced-flow or no-flow ischemic states. For patients ≤ 2.5kg, the INVOS™ Patient Monitor, model PM7100 is only intended for adjunct trend monitoring of regional hemoglobin oxygen saturation of blood tissue beneath the sensor.

It is also intended for use as an adjunct trend monitor of regional hemoglobin oxygen saturation of blood tissue beneath the sensor in any individual.

The INVOS™ Adult rSO_2 Sensor (cleared in K182868) is indicated for single patient use when cerebral/somatic monitoring of site-specific regional oxygen saturation (rSO_2) is required in patients weighing > 40 kilograms. This sensor is only intended to be used with INVOS™ Near Infrared Spectroscopy (NIRS) technology including monitoring systems and devices integrated with INVOS™ NIRS technology. For additional information regarding setup and use of the INVOS™ System including indications for use, contraindications, warnings and cautions, consult the Monitoring System Operator's Manual.

The INVOS™ Pediatric rSO_2 sensor is indicated for single patient use when cerebral/somatic monitoring of site-specific regional oxygen saturation (rSO_2) is required in patients weighing greater than 4 kg and less than 40 kilograms. This sensor is only intended to be used with INVOS™ PM7100 system with INVOS™ Near Infrared Spectroscopy (NIRS) technology. For additional information regarding setup and use of the INVOS™ PM7100 System including indications for use, contraindications, warnings and cautions, consult the Monitoring System Operator's Manual.

The INVOS™ OxyAlert NIRSensor disposable sensor Model IS is indicated for single patient use when cerebral/somatic monitoring of site-specific regional oxygen saturation (rSO_2) is required in patients weighing >2.5 kilograms and < 40 kilograms or for trend monitoring of rSO_2 of blood tissue beneath the sensor in any individual < 40kg . This sensor is only intended to be used with INVOS™ Near Infrared Spectroscopy (NIRS) technology including monitoring systems and devices integrated with INVOS™ NIRS technology. For additional information regarding setup and use of the INVOS™ System including indications for use, contraindications, warnings and cautions, consult the Monitoring System Operator's

Manual.

CONTRAINDICATIONS

The INVOS™ Adult rSO_2 sensor (cleared in K182868) and Pediatric rSO_2 are contraindicated for use on patients who exhibit allergic reactions to the adhesive tape.

The INVOS™ OxyAlert NIRSensor infant sensor has no known contraindications.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE:

The subject INVOS™ PM7100 maintains the same intended use and technological characteristics as both of its predecessors, the INVOS™ PM7100 Patient Monitor (cleared under K182868) and INVOS™ 5100C System (cleared under K082327). The subject and predicate devices have the following key similarities and differences:

- Principles of Operation: The subject and predicate INVOS™ models utilize the same principles of operation
- Indications for Use: The intended use and intended patient population (adult and pediatric patients) of the subject INVOS™ PM7100 device and primary predicate INVOS™ 5100C device are the same. The secondary predicate INVOS™ PM7100 device was cleared only for the adult population (>40 kg).
- Features: The same features within the predicate INVOS™ 5100C device are being brought over for use within the INVOS ™ PM7100 device.
- Algorithm: The same pediatric algorithm of the primary predicate INVOS™ 5100C device is being brought forward for use in the subject INVOS™ PM7100 device.
- Software/firmware: The subject INVOS™ PM7100 device incorporates changes in the software and firmware from the secondary predicate INVOS™ PM7100 device to allow for compatibility with the infant and pediatric sensors.

The subject INVOS™ Pediatric rSO_2 Sensor PMSENS71-P and predicate INVOS™ Sensor SPFB have the following key similarities and differences:

- Intended patient population: The subject PMSENS71-P sensor is intended to be used on pediatric patients within the same weight range as the predicate SPFB sensor. The PMSENS71-P sensor is intended for use on patients 4 to 40 kg, while the SPFB sensor is intended for use in patients less than 40 kg.
- Materials: The same adhesive material is utilized in the subject and predicate pediatric sensors.
- Technological characteristics: The subject and predicate pediatric sensors are electrically and optically equivalent. The primary difference is that the subject PMSENS71-P device utilizes an additional 2 LEDs and 2 infrared wavelengths for the sensor on/off detection feature.

The subject INVOS™ Infant Regional Saturation Sensor model IS and predicate OxyAlert™ Infant/Neonatal NIR Sensors models IS-C and IS-S have the following key similarities and differences:

- Application site: The subject IS sensor was developed to be used on both somatic and cerebral sites by combining the cerebral and somatic functionality of the predicate IS-S and IS-C sensors.
- Labeling: The subject IS sensor includes application instructions for use on both the cerebral and somatic sites.
- Intended patient population: The subject IS sensor and predicate IS-S and IS-C sensors are intended to be used in the infant/neonatal population.
- Design characteristics and materials: The subject IS sensor maintains the same design characteristics and materials as the predicate IS-S and IS-C sensors.
- Performance: Changes implemented in the subject IS sensor do not affect measurement of rSO_2, and dimensions associated with performance were not changed.

PERFORMANCE DATA SUMMARY:

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

Biocompatibility Testing

The biocompatibility evaluation for the INVOS™ Pediatric rSO_2 sensor, PMSENS71-P, and INVOS™ OxyAlert NIRSensor disposable sensor, IS, were conducted in accordance with International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA.

The battery of testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation

The INVOS™ PM7100 monitor, PMAC71DOC Docking station, PMAC71STAND monitor stand, PMPAMP71 preamplifier, and PMAC71RIC reusable infant sensor adapter cable are not intended to contact the patient. The INVOS™ Adult rSO2 sensor, PMSENS71-A, and PMAC71RSC reusable sensor cable (cleared in K182868) are designed for patient skin contact. INVOS™ Pediatric rSO_2 sensor, PMSENS71-P, and INVOS™ OxyAlert NIRSensor disposable sensor, IS are intended for use on intact skin only with a contact time of less than 24 hours.

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the INVOS™ PM7100 System, consisting of the PM7100 Monitor, Preamp PMPAMP71, Re-usable cables PMAC71RSC, Pediatric rSO_2 sensor PMSENS71-P, Infant rSO_2 sensor IS and Re-usable Infant sensor adaptor cable PMAC71RIC. The system complies with the ANSI/AAMI ES60601-1, IEC 62471 standards for safety and the IEC 60601-1-2 standard for EMC.

Software Verification and Validation Testing

Software verification and validation testing were conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "moderate" level of concern, due to the possibility that a malfunction, or a latent design flaw in the device could lead to an erroneous diagnosis or delay in delivery of appropriate medical care that could lead to minor injury.

Non-clinical Performance Testing

Non-clinical testing for the Pediatric rSO_2 sensor PMSENS71-P and the Infant rSO_2 sensor IS included the following:

- Mechanical
- Bend (Flexibility)
- Tail Torque
- Ambient Light
- Transport Temperature
- Storage Temperature, Humidity and Altitude
- Sensor Temperature Rise Measurement System
- Sensor EEPROM Identification

System verification for the subject device included comparative testing between the subject and predicate devices on a bench-top optical phantom to verify static rSO_2 calculation. The subject system of the INVOS™ PM7100 Monitor with either the Pediatric rSO_2 sensor, PMSENS71-P or the Infant/Neonatal sensor, IS, was compared with the respective predicate system of the INVOS™ 5100C Monitor with the Pediatric sensor SPFB or the Infant/Neonatal sensor, IS. The measured rSO2 values using the subject system are within the acceptance criteria of ±4 rSO_2 from the predicate system when measured on the same optical reference. The results demonstrated that the subject device has substantially equivalent static rSO_2 accuracy versus the predicate system when tested on bench-top optical phantoms.

Bench-top testing was performed to confirm that the system appropriately utilizes the correct algorithm depending on the type of sensor connected and raises appropriate alarms to ensure valid sensor combinations are utilized. Testing included various system configurations to evaluate the behavior of the complete INVOS™ PM7100 System with respect to operating modes (Adult, Pediatric, Infant). Results were collected to confirm that the appropriate rSO_2 algorithm is used based on the connected sensor type (via code inspection), and system verification was completed to confirm system appropriately displays data on 1 to 4 channel based on the number of preamps and sensors connected, sensor type indicator is appropriately displayed on the screen, and alarms for incompatible and mismatched sensors are appropriate provided. The results supported the conclusion that The INVOS™ PM7100 device appropriately identifies the connected sensors, alarms if an invalid combination of sensors is connected and utilizes the appropriate algorithm based on the connected sensors.

Clinical Studies
To support the substantial equivalence of the subject device with the expanded indications for use, a clinical study and a feasibility study were conducted.

The clinical study included a comparison in rSO_2 trending between the cleared INVOS™ 5100C system in conjunction with the Infant/Neonatal Sensor (predicate system) and the INVOS™ PM7100 system in conjunction with the Infant/Neonatal Sensor (subject system) on cerebral and somatic sites. The devices were evaluated during a non-invasive hypoxia study conducted on healthy, non-smoking adults and adolescent volunteers over the saturation range of approximately 70-100% SpO_2 levels. 24 subjects were given a gas mixture of medical grade oxygen and nitrogen to induce hypoxia to achieve the required minimum target SpO_2 level for each plateau of the breathing profile. The acceptance criteria was rSO_2 trend precision of less than or equal to 2.9% standard deviation of the rSO_2 trend error. The results demonstrated an acceptable measure of trend precision between the INVOS™ PM7100 in conjunction with an Infant/Neonatal IS sensor and the INVOS™ 5100C in conjunction with an Infant/Neonatal IS sensor in terms of the standard deviation of the errors, of 2.09% rSO2 for cerebral and 1.96% rSO2 for somatic.

The feasibility study included a comparison in rSO_2 performance and sensor on/off detection accuracy and timing between the cleared INVOS™ 5100C system in conjunction with the Pediatric sensor, SPFB (predicate system) and the INVOS™ PM7100 system in conjunction with the Pediatric rSO_2 sensor, PMSENS71-P (subject system).

To evaluate rSO_2 performance, the predicate and subject sensors were placed on the right and left sides of the forehead and the side placement for each sensor type was alternated between subjects. Cerebral tissue oxygenation saturation, rSO_2 data was collected at room air for 28 subjects. The acceptance criteria was the rSO_2 measured by the PMSENS71-P sensor used with the INVOS™ PM7100 and rSO_2 measured by the SPFB sensor used with the INVOS™ 5100C shall have a mean bias that does not exceed ±4% rSO_2, and the results were a mean bias equal to ±0.466% rSO_2. The study results conclude there is no significant bias in measuring rSO2 between the INVOS™ PM7100 System used in conjunction with the PMSENS71-P sensor (subject system) and the primary predicate INVOS™ 5100C with the SPFB sensor.

To evaluate sensor on/off detection accuracy and timing, a single PMSENS71-P sensor was applied and removed for 28 subjects. Four sensor off conditions were tested; 1- sensor positioned face up on a white sheet, 2-sensor positioned face down on a white sheet, 3- sensor hanging or 4- sensor positioned face up covered with a white sheet. The sensor off conditions were changes for each subject and cycled through the four conditions. The results included a percentage of 100% for successfully detecting sensor removal within 1 minute. A percentage of 100% for successfully detecting sensor application within 15 seconds. A percentage of 96.43% for successfully detecting the sensor is off the subject. A percentage of 100% for successfully detecting the sensor is on the subject. The study results demonstrate that there is acceptable performance for the sensor on/off feature in the indicated pediatric population.

CONCLUSION

The comprehensive verification and validation testing consisting of a system design analysis, bench-top tissue phantom tests, trend performance verification clinical studies, and a system comparison room air feasibility clinical study have clearly demonstrated that the INVOS™ PM7100 Patient Monitor used with the Pediatric rSO_2 Sensor, PMSENS71-P and Infant/Neonatal sensors, IS, is substantially equivalent to the predicate devices with respect to clinical use case, characteristics, and performance.