



Covidien llc  
Samir Ibrahim  
Regulatory Affairs Manager  
6135 Gunbarrel Avenue  
Boulder, Colorado 80301

January 8, 2019

Re: K182868

Trade/Device Name: INVOS PM7100 Patient Monitor, INVOS Adult rSO2 Sensor  
Regulation Number: 21 CFR 870.2700  
Regulation Name: Oximeter  
Regulatory Class: Class II  
Product Code: MUD, QEM  
Dated: October 11, 2018  
Received: October 12, 2018

Dear Samir Ibrahim:

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Neil R  
Ogden -S

Digitally signed by  
Neil R Ogden -S  
Date: 2019.01.08  
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For Binita S. Ashar, M.D., M.B.A., F.A.C.S.  
Director  
Division of Surgical Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K182868

Device Name

INVOS™ PM7100 Patient Monitor

INVOS™ Adult rSO2 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 greater than 40 kg at risk for reduced-flow or no-flow ischemic states.

The INVOS™ Adult rSO2 Sensor is indicated for single patient use when cerebral/somatic monitoring of site-specific regional oxygen saturation (rSO2) 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.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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## 510(k) SUMMARY

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807.92, provided is the 510(k) summary for INVOS™ PM7100 Patient Monitor.

### SUBMITTER INFORMATION:

Submitted By:	Covidien llc 6135 Gunbarrel Avenue Boulder, CO 80301
Contact:	Samir Ibrahim Manager Regulatory Affairs
Phone:	(720) 253-2752
Fax:	(303) 305-2212
Date of Preparation:	October 11, 2018

### DEVICE NAME:

Trade Name(s):	INVOS™ PM7100 Patient Monitor
Common/Usual Name:	Cerebral Somatic Tissue Oximeter
Classification:	Class II
Classification Name:	Oximeter
CFR Reference:	21 CFR 870.2700
Product Code:	MUD and QEM

### PREDICATE DEVICE:

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

### DEVICE DESCRIPTION:

The INVOS™ PM7100 Patient Monitor is a cerebral/somatic tissue oximeter that utilizes a near infrared diffuse reflectance spectroscopy system employing near infrared light at four wavelengths. Two wavelengths are used to estimate the percentage of hemoglobin saturated with oxygen in tissue underneath the sensor. Near infrared light at two additional wavelengths are used for the sensor on/off detection algorithm.

The subject device is non-sterile and consists of a multi-channel touch screen display, preamplifier, cables, and a single use sensor.

The device utilizes up to four detachable sensors to collect signals. Up to two preamplifiers receive signals from the sensors, digitize the signals, process the data and then estimate the current rSO<sub>2</sub> at each sensor site. The preamplifiers then transmit the measured parameter data to the monitor where the information is displayed.

### **ACCESSORIES:**

INVOS™ Adult rSO <sub>2</sub> Sensor, PM7100 and 5100C	PMSENS71-A
INVOS™ Reusable Sensor Cable for PM7100	PMAC71RSC
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 greater than 40 kg at risk for reduced-flow or no-flow ischemic states.

The INVOS™ Adult rSO<sub>2</sub> Sensor is indicated for single patient use when cerebral/somatic monitoring of site-specific regional oxygen saturation (rSO<sub>2</sub>) 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.

### **CONTRAINDICATIONS**

The INVOS™ Adult rSO<sub>2</sub> sensor is contraindicated for use on patients who exhibit allergic reactions to the adhesive tape.

### **TECHNOLOGICAL CHARACTERISTICS SUMMARY:**

The INVOS™ PM7100 Patient Monitor is a four wavelength, diffuse reflectance spectroscopy system employing near infrared light. Two wavelengths of near infrared light are used to estimate the percentage of hemoglobin saturated with oxygen in tissue underneath the sensor and two additional wavelengths are used for sensor on/off detection. An adhesive sensor containing four LED light sources and two photodiodes is applied to the skin over cerebral and somatic tissue and the returning light from two LEDs is analyzed for oxyhemoglobin and deoxyhemoglobin light absorption. Absorption signals from the photodiode closer to the light source are subtracted from those from the farther photodiode where the returning photons penetrate more deeply in the tissue. This removes the impact of absorption events originating in the outer layers of tissue that are common to both photodiodes, including the effects of skin pigmentation and subcutaneous tissues.

### **SUBSTANTIAL EQUIVALENCE STATEMENT:**

The INVOS™ PM7100 Patient Monitor has the same intended use and indications for the adult population > 40 kg, principles of operation and technological characteristics as the predicate device. The changes in the display, preamplifier and sensor do not raise any new questions of safety or effectiveness. Performance data demonstrates that the INVOS™ PM7100 Patient Monitor and the INVOS™ Adult rSO<sub>2</sub> Sensor are equivalent to the predicate.

**PERFORMANCE DATA SUMMARY:**

**NONCLINICAL TESTING:**

The INVOS™ PM7100 Patient Monitor was designed and bench tested against the performance categories noted below. When available, the applicable standards and guidance documents were used for design and testing in support of substantial equivalence.

<b>Bench Test Category</b>	<b>Guidance/Standard</b>
Essential Performance	EN 60601-1
Electrical Safety	IEC 60601-1
Electromagnetic Compatibility	IEC 60601-1-2 FDA Guidance <i>Electromagnetic Compatibility of Electrically-Powered Medical Devices</i>
Usability	IEC 60601-1-6 IEC 62366 FDA Guidance <i>Applying Human Factors and Usability Engineering to Medical Devices</i> Draft Guidance
Alarm	IEC 60601-1-8
Optical Safety	IEC 62471
Software	IEC 62304 FDA Guidance for the <i>Content of Premarket Submissions for Software Contained in Medical Devices</i> FDA Guidance <i>General Principles of Software Validation</i> FDA Guidance <i>Off-The-Shelf Software Use in Medical Devices</i>
Biocompatibility	ISO 10993-1
Mechanical and Environmental	IEC 60601-1
Cybersecurity	FDA Guidance <i>Content of Premarket Submissions for Management of Cybersecurity in Medical Devices</i>

**CLINICAL TESTING:**

Three clinical studies were conducted and completed, rSO<sub>2</sub> trend equivalence, sensor backward compatibility and sensor on/off in support the INVOS™ PM7100 Patient Monitor.

An rSO<sub>2</sub> trend equivalence clinical study was performed to demonstrate the rSO<sub>2</sub> trend precision between the INVOS™ PM7100 and the predicate device. A secondary analysis of the data for the system comparison of accuracy and precision to support device equivalency was conducted and demonstrated that rSO<sub>2</sub> values of subject and predicate are comparable. The INVOS™ PM7100 maintains the same fundamental rSO<sub>2</sub> technology as its predicate i.e., the same rSO<sub>2</sub> algorithm and the same optical and

electrical signal chain.

A sensor backwards compatibility clinical test was performed to demonstrate that the new PMSSENS71-A sensor trend accuracy is equivalent to the trend accuracy of the SAFB-SM sensor when used with the INVOS™ 5100C. A secondary analysis of the system comparison of accuracy and precision to support PMSSENS71-A sensor equivalency was conducted and demonstrated that rSO<sub>2</sub> values of both sensors are comparable. The test supports the use of the of the PMSSENS71-A sensor with the INVOS™ 5100C.

A sensor on/off detection clinical study was conducted to demonstrate that the new sensor and the new sensor on/off algorithm are capable of detecting sensor on and sensor off conditions on clinical study subjects.

The clinical studies paired with a bench study using simulated patient data demonstrate that the INVOS™ PM7100 Patient Monitor meets the same trend performance as the predicate device, the new sensor on/off feature functions as intended, and the new sensor is backwards compatible with the predicate device and is therefore deemed substantially equivalent to the predicate device.

## **CONCLUSION**

Results from comprehensive verification and validation testing consisting of a system design analysis, a bench-top tissue phantom test, trend performance validation clinical study, and a backward compatibility validation clinical study demonstrated that the INVOS™ PM7100 Patient Monitor is substantially equivalent to the predicate device with respect to clinical use case, characteristics, and performance. This equivalence allows for the subject device to support the same claims (adult only) and indications for use as the predicate device.

The result from the sensor on/off clinical study proves that the INVOS™ PM7100 Patient Monitor can effectively detect when the sensor is on and when the sensor is off the patient.

The results from the human factors validation have shown that the updated monitor/user interface with a touch screen display improves user-friendliness of the system but doesn't introduce unforeseen risk to the subject device.

The information provided in this 510(k) demonstrates the INVOS™ PM7100 Patient Monitor is substantially equivalent to the predicate device with respect to performance.