March 1, 2024

ISS Medical, Inc.
Beniamino Barbieri
President
1602 Newton Drive
Champaign, Illinois 61822

Re: K232385
Trade/Device Name: OxiplexTS200
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: MUD
Dated: August 4, 2023
Received: August 9, 2023

Dear Beniamino Barbieri:

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,

Tanisha L. Hithe -S
Tanisha L. Hithe -S
2024.03.01
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Tanisha Hithe
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control 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)*
K232385

Device Name
OxiplexTS200

Indications for Use *(Describe)*
The OxiplexTS200 tissue oximeter is intended to non-invasively estimate the percent oxygen saturation (StO2) in a volume of tissue. It is indicated for monitoring patients during circulatory or perfusion examinations of skeletal muscle or when there is a suspicion of compromised circulation. The device can be used for monitoring in Medical Clinics, laboratories and outpatient facilities.
The OxiplexTS200 should not be used as the sole basis for diagnosis or therapy. The value of these measurements in disease states has not been demonstrated.

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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Section 5: 510(k) Summary

510(k) Summary and Certification

1. Submitter's Name/Contact Person

Submitted by:
ISS Medical, Inc.
1602 Newton Drive
Champaign, IL 61822

Contact Person:
Beniamino Barbieri
President
Tel: 217.359.8681 x 11
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Summary Date: July 31, 2017

2. General Information

a. **Proprietary Name:** OxiplexTS200
b. **Common/Usual Name:** Tissue Oximeter
c. **Classification Name:** Oximeter
d. **Class:** II
e. **Product Code:** 74MUD
f. **CFR Reference:** 21 CFR 870.2700
g. **Identification of Equivalent Devices:**

InSpectra StO_2Tissue Oxygenation Monitor, Model 650 (k100915)
ViOptix ODISsey Tissue Oximeter (k042657)

3. Device Description

The ISS Medical non-invasive tissue oximeter, OxiplexTS200, is intended for use as an adjunct monitor of regional oxy- and deoxy-hemoglobin concentration, and of hemoglobin oxygen saturation of blood in tissues during circulatory or perfusion examinations of skeletal muscle or when there is a suspicion of compromised circulation.

The OxiplexTS200 is a device for use in spot-checking as well as continuous monitoring of patients in healthcare facilities. It is not intended for home use or to be used for "out of hospital" transport.

The OxiplexTS200 is an instrument system and includes the following components:

- OxiplexTS200 Unit with two sensors and phantom block
- Power cable
- Accessories (straps for sensors; strap for phantom block; dark cloth)
- ISS flash memory
- Operation Manual

- Analog Input module with USB cable (optional)
- Analog Output module with USB cable (optional)

The OxiplexTS200 uses near-Infrared Spectroscopy (NIRS), a noninvasive diagnostic tool, to offer features for the assessment and monitoring of oxygenation in tissues such as brain and muscle. Near-infrared light (in the wavelength range 700-900 nm) can penetrate several centimeters into numerous body tissues. NIRS enables continuous real time measurements of changes in the hemoglobin oxygenation state, thus providing information on tissue oxygenation and hemodynamics.

4. Indications for Use

The OxiplexTS200 tissue oximeter is intended to non-invasively estimate the percent oxygen saturation (StO2) in a volume of tissue. It is indicated for monitoring patients during circulatory or perfusion examinations of skeletal muscle or when there is a suspicion of compromised circulation. The device can be used for monitoring in Medical Clinics, laboratories and outpatient facilities. The OxiplexTS200 should not be used as the sole basis for diagnosis or therapy. The value of these measurements in disease states has not been demonstrated.

5. Comparison with Predicate Devices

ISS Medical's OxiplexTS200 System is compared to the InSpectra StO_2Tissue Oxygenation Monitor, Model 650 and the ViOptix ODISsey Tissue Oximeter in Table 1 below.

Table 5-1: Comparison to Predicate Devices

	OxiplexTS200	**InSpectra StO_2Tissue Oxygenation Monitor, Model 650 (k100915)**	**ViOptix ODISsey Tissue Oximeter (k042657)**	**Similar/ Same**
Indications for Use	The OxiplexTS200 tissue oximeter is intended to non-invasively estimate the percent oxygen saturation (StO2) in a volume of tissue. It is indicated for monitoring patients during circulatory or when there is a suspicion of	Hutchinson Technology Incorporated's InSpectra™ StO_2Tissue Oxygenation Monitor is intended for use as a noninvasive monitoring system that measures an approximated value	The ViOptix ODISsey Tissue Oximeter is intended to noninvasively estimate the percent oxygen saturation (StO_2) in a volume of tissue.	

	OxiplexTS200	InSpectra StO_2Tissue Oxygenation Monitor, Model 650 (k100915)	ViOptix ODISsey Tissue Oximeter (k042657)	Similar/ Same
Indications for Use	compromised circulation. The device can be used for monitoring in Medical Clinics, laboratories and outpatient facilities. The OxiplexTS200 should not be used as the sole basis for diagnosis or therapy. The value of these measurements in disease states has not been demonstrated.	of percent hemoglobin oxygen saturation in tissue (StO_2). The InSpectra™ StO_2Tissue Oxygenation Monitor is indicated for use in monitoring patients during circulatory or perfusion examinations of skeletal muscle or when there is a suspicion of compromised circulation.	This is performed in medical environments including physician offices, hospitals, ambulatory care, and Emergency Medical Services. The ODISsey Tissue Oximeter is indicated for use in monitoring patients during circulatory or perfusion examinations of skeletal muscle or when there is a suspicion of compromised circulation.	Similar

	OxiplexTS200	**InSpectra StO_2Tissue Oxygenation Monitor, Model 650 (k100915)**	**ViOptix ODISsey Tissue Oximeter (k042657)**	**Similar/ Same**
Principle of Operation	Light is used to probe the region of the tissue under the sensor. Light is sent through the issue at four different locations; a fraction of it returns to the surface and it is collected at set distances from the points of insertion. Optical parameters of the tissue are determined and hence the concentration of oxy- and deoxy-hemoglobin. The tissue oxygen saturation is derived.	Diffuse reflectance spectroscopy. Light is used to probe a cross section of the microvasculature of tissue (mixed bed of arterioles, capillaries, and venuoles). The light returning from tissue, after having passed through tissues, for hemoglobin in its oxygenated and deoxygenated forms in the optically sampled region. The tissue oxygen saturation (%StO_2), a value reflecting percentage of oxygenated hemoglobin in the sampled microvasculature of tissue is calculated.	Diffuse reflectance spectroscopy. Light is used to probe a cross section of the microvasculature of tissue (mixed bed of arterioles, capillaries and venuoles). The light returning from tissue, after having passed through tissues, for hemoglobin in its oxygenated and deoxygenated forms in the optically sampled region. The tissue oxygen saturation (%StO_2), a value reflecting percentage of oxygenated hemoglobin in the sampled microvasculature of tissue, is calculated.	Similar
Range (StO_2)	0-100%	0-99%	0-100%	Similar
Accuracy [parameter StO2]	50-100%: 2% 26-49%: 3% 0-25%: 10%	70-99%; 1.63 StO_2 units 0-70%; 2.94 StO_2 units	80-100%: 2.7% 60-80%: 2.3% 40-60%: 5.2% 10-40%: 13.3%	Similar
Alarm Limit Range	Visual alarms when value is below custom set threshold.	Visual alarms for error conditions	Audio and visual alarms when range limit is exceeded	Same for ViOptix; different for InSpectra
Measures Near-infrared Wavelength	Yes	Yes	Yes	Same

	OxiplexTS200	**InSpectra StO_2Tissue Oxygenation Monitor, Model 650 (k100915)**	**ViOptix ODISsey Tissue Oximeter (k042657)**	**Similar/ Same**
Sensor	Re-useable	Single use; disposable	Single use; disposable	Different
Sample Acquisition	Fiber optic bundle placed in contact with skin.	Fiber optic probe placed on intact skin	Fiber optic probe placed on intact skin	Same
Features (e.g., alarms, display and indicators, modes)	Several errors and alarms are reported by the software during the operation of the instrument: a. Overload Warning (when the signal from the environment saturates the detectors); b. Signal Strength Warning (regarding the placement of the sensors on the patient; c. Visual Alarm for set thresholds of [THC] and oxygen saturation; d. Overvoltage warning. e. Warnings resulting from Error condition tests (AC slope, regression coefficient, phase standard deviation, out of range optical parameters).	• Audiovisual high/low StO_2 error condition, • Defective LED or cable sensor • Communication error • Over temperature • Cable not connected Customizable StO_2 alarm limits and notification of error conditions	System will perform self-test when power is turned on. Visual and audible alarms include: low StO_2, high StO_2, StO_2 drop rate and low battery. Visual alarms include: inadequate patient contact, sensor laser ON, and AC power ON. Alarm volume 50 to 80 dbA at 30cm (1 foot). Single-channel (default) or dual channel (applies to consoles with dual channel option when 2 sensors are attached.) 3-cell Lithium Ion Battery with 30 minute minimum.	Similar
Time to first reading	Continuous reading with up to 8 hours trended display. Max display update rate 0.5 seconds	Continuous reading with up to 8 hours trended display. Display update rate 2 seconds.	~20 seconds	Same for InSpectra; different for ViOptix

	OxiplexTS200	**InSpectra StO_2Tissue Oxygenation Monitor, Model 650 (k100915)**	**ViOptix ODISsey Tissue Oximeter (k042657)**	**Similar/ Same**
Number of different wavelengths of light emitted	Two (2); 690nm and 830nm	Four (4); 680, 720, 760, and 800nm	Two (2); 690nm and 830nm	Same for ViOptix; different for InSpectra
Battery	Not available, (the instrument does not operate with a battery)	Lithium battery; capacity 2 hours (new/full charge); Life 300 full charge/discharge cycles	Lithium battery	Different
Product Laser Rating	Class I	Class I	Class 3R	Same for InSpectra; different from ViOptix

Similarities between the OxiplexTS200 and the predicates include:

1. The intended use for all three devices is similar.
2. The principles of operation are similar.
3. The range and accuracy are similar.
4. All three devices measure near-infrared wavelength.
5. The sample acquisition is the same for all three devices.
6. The safety specifications are the same.
7. The features of the three devices are similar.

Differences between the OxiplexTS200 and the predicates include:

1. The OxiplexTS200 and ViOptix have both audio and visual alarms; the InSpectra has only visual alarms.
2. The InSpectra and ViOptix have disposable sensors; the OxiplexTS200 has reusable sensors.
3. The OxiplexTS200 and InSpectra have continuous readings with up to 8 hours trending displayed; the ViOptix has 20 second time to read.
4. The OxiplexTS200 and ViOptix have two (2) different wavelengths of light emitted; InSpectra has four (4).
5. The InSpectra and ViOptix have battery option; OxiplexTS200 does not have a battery option.
6. OxiplexTS200 is considered to be a Class I laser product (as the InSpectra), while the ViOptix is classified as a Class 3R laser product.

6. Performance Test - Bench

The differences in the technological character between the OxiplexTS200 and the predicates do not raise new types of question regarding safety and effectiveness. In response to the reviewer's request that ISS Medical conducts a direct comparison of the OxiplexTS200 with a predicate instrument, it was arranged to compare it to the ODISey Tissue Oximeter model OXY-2 by Vioptix Inc. The comparison measurements were acquired in the Biomedical Optics Research Laboratory directed by Professor Martin Wolf at the Department of Neonatology at University Hospital Zürich in Zürich, Switzerland.

The staff and equipment there enabled us to conduct a series of simultaneous SO2 measurements using the Vioptix predicate device and the OxiplexTS200 on a phantom containing human blood diluted in an optically scattering medium to simulate a physiologically appropriate level of tissue hemoglobin concentration [tHb] and a physiologically realistic optical scattering and absorption properties. Measurements were made at three levels; from physiological levels to increasingly higher concentrations. The primary comparison of interest is the relation of the OxiplexTS200 percent oxygen saturation [SO2%] estimates with the Vioptix SO2% estimates. These are presented in section 19 performance bench testing where it can be seen that for physiologically realistic tissue hemoglobin concentrations [tHb] both instruments report nearly identical values over the range of 20% to 98% SO2. The presence of the pigmented "skin" filter had no discernable effect on either instrument.

7. Performance Testing- Clinical

We conducted testing using the OxiplexTS200 and the Vioptix devices to compare StO2 readings from a total of 25 human subjects.

Measurements were acquired over the brachioradialis, the largest muscle in the forearm, and over the thenar of the thumb, a complex region of small muscles and connective tissue. In addition to baseline measures of StO2, we varied StO2 by occluding blood flow to the arm both completely (venous and arterial occlusion) and partially (venous occlusion only), using a blood pressure cuff on the upper arm.

We found that the rate of change of StO2 after both types of occlusions was very similar for both instruments, and baseline measurements on the thenar were not statistically different, while the two instruments gave different estimates of StO2 after two minutes of occlusion at both locations, and on the arm at baseline.

These results are consistent with the results of our previous in vitro comparison of these two instruments which demonstrated that at physiologically realistic levels of [tHb] the OxiplexTS200™ and ViOptix ODISsey instruments provided essentially identical sensitive, reliable and accurate measurements of StO2.

ISS Medical Inc. has also conducted human factors testing to verify and demonstrate the safety and effectiveness of the OxiplexTS200 for its intended users, use and environment.
Most of the tests mimic the actual daily use of the system. The primary goal of these studies was to evaluate if the device operators are able to accomplish routine tasks with the provided instructions and to assess the clarity of the Instructions For Use (IFU).

Based on the results of the usability studies, the majority of users would be able to make successful and accurate measurements on first use of the device. We conclude that the device could be used effectively without any changes to the user interface.

8. Performance Testing

Bench testing and biocompatibility testing was conducted to demonstrate that the OxiplexTS200 functions as intended. The OxiplexTS200 is designed to conform to the applicable requirements of electrical safety, laser safety and electromagnetic compatibility requirements as summarized below:

- Evaluation of Risk Management in accordance with **IEC 60601-1 3rd Ed. and ISO 14971.**
- Evaluation to **60601-1 (3.1 Edition) IEC, EN, ANSI/AAMI, and CSA.** Includes European, US, and Canadian National differences.
- Evaluation of Programmable Electrical Medical Systems (PEMS) compliance, using **IEC 62304:2006** – (Software)
- Laser classification testing according to **IEC 60825-1 2nd Ed.** for two laser diodes (830nm and 690nm)
- Evaluation of Usability compliance, **using IEC 60601-1-6 :2010** Collateral standard.
- Full EMC evaluation for mains powered device using **EN/IEC 60601-1-2:2007**.
- Testing for biocompatibility **(ISO 10993-5:2009)**

All testing met specified requirements. Test reports were provided in the submission as Appendices 4, 6 and 7.

9. Conclusions

The OxiplexTS200 device that is the subject of this 510k pre-market notification, is the same or similar in design, intended use, principles of operation, and technological

characteristics, compared to the predicate devices. Differences of the subject device's output parameters compared to those of the predicate devices' output parameters do not raise new types of questions regarding safety and effectiveness, and performance testing provided in this 510k supports that the device can be used safely and effectively for the proposed indications for use. The OxiplexTS200 device that is the subject of this 510K is considered to be substantially equivalent to the predicate devices.