ViOptix, Inc.
% Valerie Defiesta-Ng
Vice President, Regulatory Affairs
Experien Group, LLC
224 Airport Parkway, Suite 250
San Jose, California 95110

September 16, 2019

Re: K191676
Trade/Device Name: Intra.Ox 2.0 Handheld Tissue Oximeter
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: MUD
Dated: June 21, 2019
Received: June 24, 2019

Dear Valerie Defiesta-Ng:

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,

Neil R.P. Ogden, MS
Assistant Director, THT4A4
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191676

Device Name
Intra.Ox™ 2.0 Handheld Tissue Oximeter

Indications for Use *(Describe)*
The Intra.Ox™ 2.0 Handheld Tissue Oximeter is intended to non-invasively estimate the percent oxygen saturation (StO_2) in a volume of tissue.
The Intra.Ox™ 2.0 Handheld Tissue Oximeter is indicated for use in monitoring patients during circulatory or perfusion examinations.
The Intra.Ox™ 2.0 Handheld Tissue Oximeter is intended to be used by physicians, surgeons, nurses, or other skilled users in a medical environment.
The Intra.Ox™ 2.0 Handheld Tissue Oximeter should only be used on adult patients.

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) Notification K_191676_____

GENERAL INFORMATION [807.92(a)(1)]

Applicant:

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USA
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224 Airport Parkway, Suite 250
San Jose, CA, 95110
USA

Date Prepared: June 21, 2019

DEVICE INFORMATION [807.92(a)(2)]

Trade Name:

Intra.Ox™ 2.0 Handheld Tissue Oximeter

Generic/Common Name:

Oximeter, Tissue Saturation

Classification:

21 CFR§870.2700

Product Code:

MUD

PREDICATE DEVICE(S) [807.92(a)(3)]

Intra.Ox™ Handheld Tissue Oximeter (K163472)

DEVICE DESCRIPTION [807.92(a)(4)]

The ViOptix Intra.Ox 2.0 Handheld Tissue Oximeter is a sterile, cordless, battery-powered device that non-invasively estimates the percent oxygen saturation (StO_2) in a volume of tissue. The device includes three components and an accessory:

- Main Unit: a re-usable module consists of light sources, detectors, and processing electronics to convert measurements of reflected light into an estimate of StO_2;
- Sheath: a single-use, sterile Sheath placed around the Main Unit during device use (provided in the Disposable Kit);
- Battery Pack: a single-use battery (provided in the Disposable Kit) that is paired with the Main Unit to provide power; and
- Quality Control (QC) Target: a single-use accessory (provided in the Disposable Kit) that provides an optical check once the Sheath is placed around the Main Unit.

The device uses spatially resolved optical measurements at five wavelengths. The device performs measurements on the patient by direct physical contact to the patient's tissue and displays the StO_2 estimate on the built-in screen.

The device shares the same Indications for Use and the same technological characteristics as the predicate device, including Principle of Operation, StO_2 measured parameters, accuracy and range, energy delivered and power source.

INDICATIONS FOR USE [807.92(a)(5)]

The Intra.Ox™ 2.0 Handheld Tissue Oximeter is intended to non-invasively estimate the percent oxygen saturation (StO_2) in a volume of tissue.

The Intra.Ox™ 2.0 Handheld Tissue Oximeter is indicated for use in monitoring patients during circulatory or perfusion examinations.

The Intra.Ox™ 2.0 Handheld Tissue Oximeter is intended to be used by physicians, surgeons, nurses, or other skilled users in a medical environment.

The Intra.Ox™ 2.0 Handheld Tissue Oximeter should only be used on adult patients.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES [807.92(a)(6)]

The technological characteristics of the Intra.Ox 2.0 Handheld Tissue Oximeter are substantially equivalent to the predicate device, the Intra.Ox Handheld Tissue Oximeter (K163472). The table below lists the technological characteristics of the proposed device and predicate device and provides rationale to support a determination of substantial equivalence. Any differences between the devices do not raise any different questions of safety or efficacy.

Feature	Intra.Ox Handheld Tissue Oximeter Primary Predicate Device	Intra.Ox 2.0 Handheld issue Oximeter Subject Device	Substantial Equivalence Rationale
510(k) Number	K163472	K191676	--
Indications for Use	The Intra.Ox Handheld Tissue Oximeter is intended to non-invasively estimate the percent oxygen saturation (StO_2) in a volume of tissue. The Intra.Ox Handheld Tissue Oximeter is indicated for use in monitoring patients during circulatory or perfusion examinations. The Intra.Ox Handheld Tissue Oximeter is intended to be used by physicians, surgeons, nurses, or other skilled users in a medical environment. The Intra.Ox Handheld Tissue Oximeter should only be used on adult patients.	The Intra.Ox™ 2.0 Handheld Tissue Oximeter is intended to non-invasively estimate the percent oxygen saturation (StO_2) in a volume of tissue. The Intra.Ox™ 2.0 Handheld Tissue Oximeter is indicated for use in monitoring patients during circulatory or perfusion examinations. The Intra.Ox™ 2.0 Handheld Tissue Oximeter is intended to be used by physicians, surgeons, nurses, or other skilled users in a medical environment. The Intra.Ox™ 2.0 Handheld Tissue Oximeter should only be used on adult patients.	Same
Measured Parameters	Tissue oxygen saturation (% StO_2)	Tissue oxygen saturation (% StO_2)	Same
Operating Principle	Spectrophotometric oximetry	Spectrophotometric oximetry	Same
Energy Delivered	Near-infrared light Source: LED chips Wavelengths: 730nm, 760mm, 810mm, 845mm, and 895mm	Near-infrared light Source: LED chips Wavelengths: 730nm, 760mm, 810mm, 845mm, and 895mm	Same
Single Patient Use or Reusable	Main Unit – Single Patient Use	Main Unit – Reusable Sheath – Single Patient Use Battery Pack – Single Patient Use Quality Control Target – Single Patient Use	Similar The difference in use of the Main Unit of the Subject Device does not raise different questions related to safety and effectiveness, as demonstrated by verification and validation testing.
Power Source	Battery powered Battery type: 4 Lithium AA Battery voltage 6V total	Battery powered Battery type: 4 Lithium AA Battery voltage 6V total	Same
Measurement Range	1-99% StO_2	1-99% StO_2	Same

Feature	Intra.Ox Handheld Tissue Oximeter	Intra.Ox 2.0 Handheld issue Oximeter	Substantial Equivalence Rationale
Physical Design	Ergonomic hand-held design for range of hand sizes, includes thumb rest, ambidextrous use	Ergonomic hand-held design for range of hand sizes, includes thumb rest, ambidextrous use Device contains a disposable kit that contains a single-use Battery Pack and sterile single-use disposable sheath.	Not the same. The difference in physical design does not raise different questions related to safety and effectiveness, as demonstrated by verification and validation testing.
Dimensions and Weight	7in. x 2.9in x 3in. L x W x H	7.3" x 2.7" x 3.1" L x W x H	Not the same The differences in physical dimensions do not raise different questions related to safety and effectiveness, as demonstrated by verification and validation testing.
Housing Materials	Polycarbonate	Polycarbonate	Same

SUBSTANTIAL EQUIVALENCE

The Intra.Ox 2.0 Handheld Tissue Oximeter is substantially equivalent to the predicate device with regard to intended use, Indications for Use, principle of operation and fundamental scientific technology. Any differences in the technological characteristics between the devices do not raise any different questions of safety or effectiveness. Thus, the Intra.Ox 2.0 Handheld Tissue Oximeter is substantially equivalent to the predicate device.

PERFORMANCE DATA [807.92(b)]

All necessary bench and clinical testing was conducted on the Intra.Ox 2.0 Handheld Tissue Oximeter to support a determination of substantial equivalence to the predicate device. The tests performed include:

- Biocompatibility
  - Cytotoxicity MEM Elution
  - Guinea Pig Maximization Sensitization
  - Intracutaneous Reactivity Irritation
  - System Toxicity
  - Material Mediated Pyrogenicity
- Mechanical Testing
- Sterilization Validation
- Packaging, Shelf-Life and Transportation Testing
- Software Verification and Validation
- Heterogeneous Blood Phantom Study

- Human Factors Usability Study
- Non-Significant Risk Clinical Study

The collective performance testing demonstrates that the Intra.Ox 2.0 Handheld Tissue Oximeter does not raise any different questions of safety or effectiveness when compared to the predicate device. The results of performance testing demonstrate that the Intra.Ox 2.0 Handheld Tissue Oximeter performs as intended.

[807.92(b)(1)]Non-clinical Testing Summary:

In a heterogenous phantom study, measurements were made using the Intra.Ox 2.0 Handheld Tissue Oximeter in a heterogeneous phantom prepared with swine whole blood using an Intralipid solution to mimic tissue scattering and compared to a "gold standard" blood co-oximeter. The results show that the Intra.Ox 2.0 Handheld Tissue Oximeter is substantially equivalent to the predicate device in limits of agreement to the gold standard, as well as 95% confidence intervals in slope and intercept. These data support the conclusion that the Intra.Ox 2.0 Handheld Tissue Oximeter provides as good or better agreement to the gold standard over the clinically relevant range than the predicate Intra.Ox Handheld Tissue Oximeter.

[807.92(b)(2)]Clinical Testing Summary:

Clinical performance was determined by measuring tissue oxygen saturation (StO_2) with the Intra.Ox 2.0 Handheld Tissue Oximeter and the predicate Intra.Ox Handheld Tissue Oximeter during transient ischemic events on healthy human volunteers, which temporarily mimics compromised tissue via a non-significant risk (NSR) IRB-approved study. A total of 18 data sets from 18 subjects, who were near-evenly distributed over age, gender, and skin color as determined by the Fitzpatrick skin type, were analyzed.

There was excellent agreement in shape of the deoxygenation curve observed during ischemic events between the Intra.Ox 2.0 Handheld Tissue Oximeter and the predicate device for each analyzed subject. A direct comparison with paired data showed good agreement considering the physiological variances inherent between measurement sites.

Figure 1 shows the similarities in values for healthy tissue (65% [Intra.Ox 2.0 Handheld Tissue Oximeter] and 61% [predicate Intra.Ox]) and mean desaturation dynamic range of 27 percentage points (both devices) agrees well with literature-reported values of skin and muscle transient ischemia.

Importantly, the Intra.Ox 2.0 Handheld Tissue Oximeter and predicate Intra.Ox devices measure similar ranges of StO_2 values for both healthy and compromised tissue, thus demonstrating substantial equivalence.

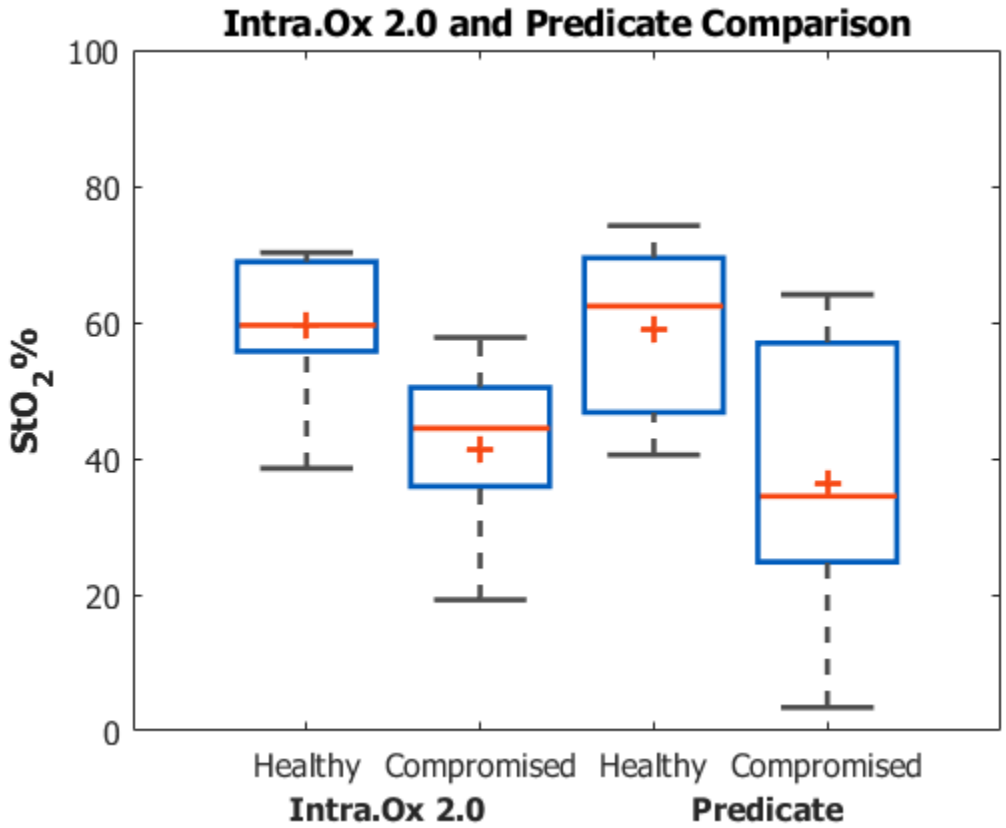

Figure 1: Boxplot Demonstrating Comparable StO_2 Values for Intra.Ox 2.0 and Predicate Device for Healthy and Compromised Tissue.

Performance Standards

Compliance to the following performance standards were followed to conduct the performance tests as listed above.

- ASTM F2096:2011, Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)
- ISO 10993-1:2009, Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process
- ISO 10993-2:2006, Biological evaluation of medical devices — Part 2: Animal welfare requirements
- ISO 10993-5:2009, Biological evaluation of medical devices — Part 5: Tests for *in vitro* cytotoxicity
- ISO 10993-10:2010, Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization
- ISO 10993-12:2012, Biological evaluation of medical devices — Part 12: Sample preparation and reference materials
- ISO 13485:2003, Medical devices — Quality management systems - Requirements for regulatory purposes
- BSI BS EN ISO 14971:2012, Medical devices — Application of risk management to medical devices
- ISTA 2A:2011, Partial Simulation Performance Tests

CONCLUSIONS [807.92(b)(3)]

The Intra.Ox 2.0 Handheld Tissue Oximeter and the predicate Intra.Ox Handheld Tissue Oximeter have the same Indications for Use and utilize the same technological characteristics which do not raise different questions of safety or effectiveness. The performance data show that the Intra.Ox 2.0 Handheld Tissue Oximeter is safe and performs as intended and as such demonstrates substantial equivalence compared to the predicate device.