May 3, 2022

ViOptix, Inc.
℅ Valerie Defiesta-Ng
Vice president, Reuglatory Affairs
Veranex, Inc. (formerly Experien Group, LLC)
224 Airport Parkway, Suite 250
San Jose, California 95110

Re: K221010
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: April 4, 2022
Received: April 5, 2022

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,

Purva Pandya, D.Eng.
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)*
K221010

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 (StO2) 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.

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510(k) Notification K221010

GENERAL INFORMATION [807.92(A)(1)]

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Date Prepared: April 22, 2022

DEVICE INFORMATION [807.92(A)(2)]

Classification:
21 CFR§870.2700

Product Code:
MUD

Trade Name:
Intra.Ox™ 2.0 Handheld Tissue Oximeter

Generic/Common Name:
Oximeter, Tissue Saturation

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

Intra.Ox™ 2.0 Handheld Tissue Oximeter (K191676)

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 (provide in the Disposable Kit); and
- Battery Pack: a single-use battery (provided in the Disposable Kit) that is paired with the Main Unit to provide power.

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 Intra.Ox 2.0 Handheld Tissue Oximeter is a single-use disposable constructed from biocompatible materials that can tolerate bodily fluids and other liquids such as disinfectants and marking materials.

The device shares the same indication for use and the same technological characteristics as the predicate device (K191676), 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 modified Intra.Ox 2.0 Handheld Tissue Oximeter are substantially equivalent to the predicate device, Intra.Ox 2.0 Handheld Tissue Oximeter (K191676). Table 1 lists the technological characteristics of the predicate and modified devices 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.

Table 1: Summary of Technological Characteristics

Feature	Predicate Intra.Ox 2.0 Handheld Tissue Oximeter	Modified Intra.Ox 2.0 Handheld Tissue Oximeter	Substantial Equivalence Rationale
510(k) Number	K191676	TBD	--
Indications for Use	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.	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.	N/A (same)
Measured Parameters	Tissue oxygen saturation (% StO_2)	Tissue oxygen saturation (% StO_2)	N/A (same)
Principle of Operation	Spectrophotometric oximetry	Spectrophotometric oximetry	N/A (same)
Energy Delivered	Near-infrared light Source: LED chips Wavelengths: 730, 760, 810, 845, and 895 nm	Near-infrared light Source: LED chips Wavelengths: 730, 760, 810, 845, and 895 nm	N/A (same)
Single Patient Use?	Yes, the Sheath is single patient use. The Main Unit is re-usable after proper cleaning.	Yes, the Sheath is single patient use. The Main Unit is re-usable after proper cleaning.	N/A (same)
Power Source	Battery Powered Battery Type: 4 Lithium AA Battery Voltage: 6 V total	Battery Powered Battery Type: 4 Lithium AA Battery Voltage: 6 V total	N/A (same)
StO_2 Measurement Range	StO_2 displayed range shall be an integer between 1 to 99%.	StO_2 displayed range shall be an integer between 1 to 99%.	N/A (same)
Physical Design	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.	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.	N/A (same)

Feature	Predicate Intra.Ox 2.0 Handheld Tissue Oximeter	Modified Intra.Ox 2.0 Handheld Tissue Oximeter	Substantial Equivalence Rationale
Dimensions and Weight	7.3" x 2.7" x 3.1" L x W x H Less than 1 lb	7.3" x 2.7" x 3.1" L x W x H Less than 1 lb	N/A (same)
Components	Main Unit, Sheath, Battery Pack and Quality Control Target	Main Unit, Sheath, and Battery Pack	Similar components. The principle of operation remains the same for both devices. The removal of the Quality Control Target does not raise different questions of safety and effectiveness as demonstrated by performance testing.

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 modified Intra.Ox 2.0 Handheld Tissue Oximeter is substantially equivalent to the predicate device.

SUMMARY OF DESIGN MODIFICATION

The following design modifications have been implemented and do not affect the intended use, the Indications for Use, or alter the fundamental scientific technology of the device. ViOptix is proposing modifications to the cleared Intra.Ox 2.0 Handheld Tissue Oximeter (K191676) to optimize the design and improve manufacturability.

- The robustness of the latch-detection functions for sheath closure was improved.
- Adhesive was removed from the inside of the sheath window, a sterile pressure-relief vent was added to the lid, and the optical target was removed for the kit.
- An averaging functionality was added with screen modification to display both "live" and "average" readings.
- The removal of two non-functional components from a device Printed Circuit Board Assembly (PCBA).

PERFORMANCE DATA [807.92(B)]

All necessary bench testing was conducted on the modified Intra.Ox 2.0 Handheld Tissue Oximeter to support a determination of substantial equivalence to the predicate device. Tests performed included:

- Mechanical Testing
- Sterility Testing
- Latch Testing
- Shelf-Life and Transport Testing
- Software Verification and Validation

- Heterogeneous Blood Phantom 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 testing was not required to demonstrate substantial equivalence.

CONCLUSION [807.92 (b) (3)]

Nonclinical performance testing has been performed on the Intra.Ox 2.0 Handheld Tissue Oximeter to evaluate the overall performance of the device. The results confirm that the Intra.Ox 2.0 Handheld Tissue Oximeter meets its specifications and meets requirements for its intended use. The Intra.Ox 2.0 Handheld Tissue Oximeter is substantially equivalent to the predicate device.