November 16, 2017

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

Re: K163472
Trade/Device Name: Intra.Ox Handheld Tissue Oximeter
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: MUD
Dated: September 20, 2017
Received: September 21, 2017

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K163472

Device Name
Intra.Ox™ Handheld Tissue Oximeter

Indications for Use *(Describe)*

The Intra.Ox™ Handheld Tissue Oximeter is intended to non-invasively estimate the percent oxygen saturation (StO2) 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.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) SUMMARY

510(k) Notification K163472

GENERAL INFORMATION [807.92(A)(1)]

Applicant:
ViOptix, Inc.
39655 Eureka Drive
Newark, CA 94560-4806
USA
Phone: 510-226-5860
Fax: 510-226-5864

Contact Person:
Valerie Defiesta-Ng
Senior Director, Regulatory Affairs
Experien Group, LLC
224 Airport Parkway, Suite 250
San Jose, CA 95110
USA
Phone: 408-400-0856
Fax: 408-400-0865
Email: valerie@experiengroup.com

Date Prepared: November 13, 2017

DEVICE INFORMATION [807.92(A)(2)]

Classification:
21 CFR§870.2700

Product Code:
MUD

Trade Name:
Intra.Ox™ Handheld Tissue Oximeter

Generic/Common Name:
Oximeter, Tissue Saturation

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

Intra.Ox™ Handheld Tissue Oximeter (K133983)

510(k) SUMMARY

DEVICE DESCRIPTION [807.92(A)(4)]

The ViOptix Intra.Ox™ 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 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 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.

ViOptix has made modifications to the cleared Intra.Ox Handheld Tissue Oximeter (K133983) to optimize the design and improve manufacturability. The modified device shares the same indication for use and the same technological characteristics as the cleared device, including principle of operation, StO2 measured parameters, accuracy and range, energy delivered and power source.

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

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.

TECHNOLOGICAL CHARACTERISTICS

The technological characteristics of the modified Intra.Ox Handheld Tissue Oximeter are substantially equivalent to the predicate device, Intra.Ox Handheld Tissue Oximeter (K133983). Table 1 lists the technological characteristics of the modified and predicate devices and provides rationale to support a determination of substantial equivalence. Any differences between the devices do not raise any different issues of safety or efficacy.

510(k) SUMMARY

Table 1. Summary of Technological Characteristics

Feature	Predicate Intra.Ox Handheld Tissue Oximeter	Modified Intra.Ox Handheld Tissue Oximeter	Substantial Equivalence Rationale
510(k) Number	K133983	TBD	--
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 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 Intended Use of the Device is identical to the predicate. The addition of user information and patient population provides clarity to the use of the device.
Measured Parameters	Tissue oxygen saturation (% StO_2)	Tissue oxygen saturation (% StO_2)	N/A (same)
Operating Principle	Spectrophotometric oximetry	Spectrophotometric oximetry	N/A (same)
Energy Delivered	Near-infrared light Source: LED chips Wavelengths: 760 mm, 810 mm, 850 mm, and 900 mm	Near-infrared light Source: LED chips Wavelengths: 730 nm, 760 mm, 810 mm, 845 mm, and 895 mm	The difference in wavelengths of the modified device does not raise any different issues of safety or efficacy.
Single Patient Use	Yes	Yes	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)
Measurement Range	1-99% StO_2	1-99% StO_2	N/A (same)
Physical Design	Ergonomic hand-held design for range of hand sizes, ambidextrous use	Ergonomic hand-held design for range of hand sizes, includes thumb rest, ambidextrous use	The difference in physical design does not raise any different issues of safety or efficacy.
Dimensions and Weight	3 in. x 7 in. Less than 1 lb.	3 in. x 7 in. Less than 1 lb.	N/A (same)
Housing Materials	Polycarbonate	Polycarbonate	N/A (same)
Aperture Plate Material	Delrin	Delrin/Polish	Both devices are biocompatible per ISO 10993-1

SUBSTANTIAL EQUIVALENCE

The Intra.Ox 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 issues of safety or efficacy. Thus, the modified Intra.Ox Handheld Tissue Oximeter is substantially equivalent to the predicate device.

PERFORMANCE DATA [807.92(B)]

All necessary performance testing was conducted on the modified Intra.Ox 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
- Transportation Testing
- Software Verification and Validation
- Heterogeneous Blood Phantom Study (Summary or results provided)
- Non-significant Risk Clinical Study (Summary of results provided)

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

Heterogeneous Phantom Study – Non-clinical

In this study, measurements were made using the modified Intra.Ox 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 modified Intra.Ox 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 modified Intra.Ox device provides as good or better agreement to the gold standard over the clinically relevant range than the predicate Intra.Ox Handheld Tissue Oximeter.

Clinical Study

Performance was determined by measuring tissue oxygen saturation (StO_2) with the modified Intra.Ox Handheld Tissue Oximeter and the predicate Intra.Ox Handheld Tissue Oximeter during transient ischemic events on healthy human volunteers that temporarily mimics compromised tissue. A total of 19 data sets from 19 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 and predicate device for each analyzed subject. A direct comparison

with paired data showed good agreement considering the physiological variances inherent between measurement sites.

Reference Figure 1. The similarities in values for healthy tissue (65% [modified Intra.Ox] 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 modified Intra.Ox and predicate Intra.Ox devices measure similar ranges of StO_2 values for both healthy and compromised tissue, thus validating substantial equivalence.

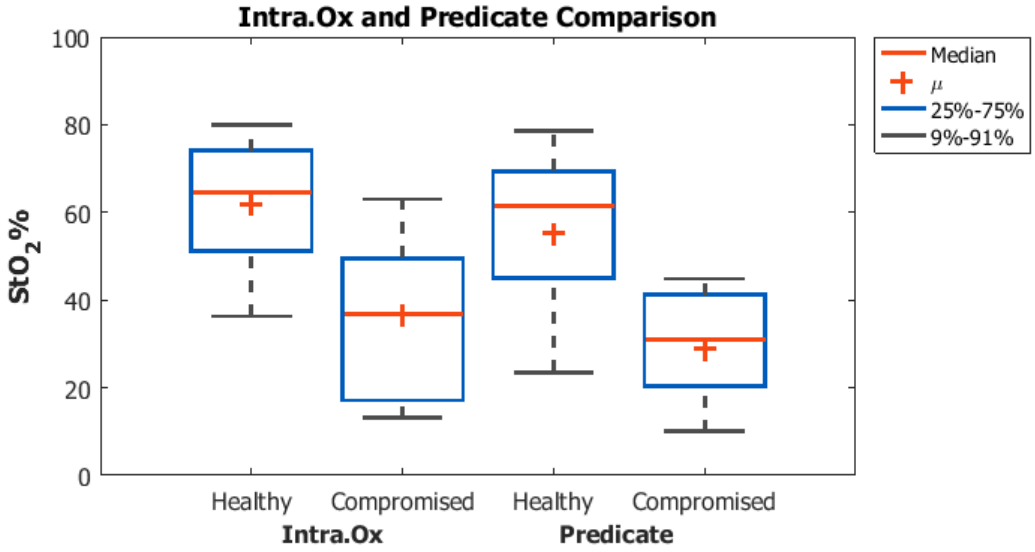

Figure 1. Boxplot demonstrating comparable dynamic range values for modified Intra.Ox and predicate devices between healthy and compromised tissues.

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

SUMMARY

The modified Intra.Ox™ Handheld Tissue Oximeter and the predicate Intra.Ox™ Handheld Tissue Oximeter have the same intended use and has similar technology that does not raise new types of questions of safety or effectiveness. The performance data show that the modified Intra.Ox provides reasonable assurance of safety and effectiveness to demonstrate substantial equivalence.