February 28, 2024

ViOptix, Inc.
% Valerie Defiesta-Ng
Regulatory Consultant for ViOptix, Inc. / Vice President, Regulatory Affairs, Veranex, Inc.
Veranex, Inc.
224 Airport Parkway
Suite 250
San Jose, California 95110

Re: K233488
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: January 26, 2024
Received: January 29, 2024

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 (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
2024.02.28
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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)*
K233488

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, including bowel 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.

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

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510(k) #: K233488

510(k) Summary

Prepared on: 2024-02-28

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	ViOptix, Inc.
Applicant Address	39655 Eureka Drive Newark CA 94560 United States
Applicant Contact Telephone	(510) 226-5860
Applicant Contact	Mr. Scott Coleridge
Applicant Contact Email	secoleridge@vioptix.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Intra.Ox™ 2.0 Handheld Tissue Oximeter
Common Name	Oximeter
Classification Name	Oximeter, Tissue Saturation
Regulation Number	870.2700
Product Code	MUD

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K221010	Intra.Ox™ 2.0 Handheld Tissue Oximeter	MUD

Device Description Summary

21 CFR 807.92(a)(4)

The ViOptix Intra.Ox™ 2.0 Handheld Tissue Oximeter (device) is a sterile, cordless, battery-powered device that non-invasively estimates the percent oxygen saturation (StO2) 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 StO2;
- 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 StO2 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 technological characteristics as the predicate device (K221010), including principle of operation, StO2 measured parameters, accuracy and range, energy delivered and power source.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The Intra.Ox™ 2.0 Handheld Tissue Oximeter is intended to non-invasively estimate the percent oxygen saturation (StO2) in a volume of tissue, including bowel 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.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The proposed Intra.Ox™ 2.0 Handheld Tissue Oximeter and the cleared Intra.Ox™ 2.0 Handheld Tissue Oximeter (K221010) have the same intended use and share the same technological characteristics. ViOptix, Inc. is proposing modifications to the predicate Intra.Ox™ 2.0 Handheld Tissue Oximeter (K221010) Indications for Use statement and Precautions statement. The differences outlined in this Traditional 510(k) premarket notification do not affect the intended use or alter the fundamental scientific technology of the device. The modification to the Indications for Use statement (including bowel tissue) is presented to specify a particular tissue which already falls under the general tissue indication of the device. The modification to the Precautions statement language (stool-filled tissue) provides an added condition to avoid improper device placement.

Technological Comparison

21 CFR 807.92(a)(6)

The proposed Intra.Ox™ 2.0 Handheld Tissue Oximeter and the cleared Intra.Ox™ 2.0 Handheld Tissue Oximeter (K221010) share the same technological characteristics.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

The animal study demonstrates that the Intra.Ox™ 2.0 Handheld Tissue Oximeter responds appropriately to the presence of transient ischemia induced by arterial occlusion and satisfies similar acceptance criteria to the prior clinical validation fingertip study, which was previously presented in K191676. This was the initial 510(k) that was submitted for the Intra.Ox™ 2.0 Handheld Tissue Oximeter.

The human study, Gonzalez-Jacobo et al., demonstrates that the Intra.Ox™ 2.0 Handheld Tissue Oximeter provides clinically relevant information regarding bowel ischemia across multiple surgical procedures in human patients, providing comparable information to the existing standard of care.

An animal study was conducted and human clinical data from published scientific literature was included to demonstrate that the Intra.Ox™ 2.0 Handheld Tissue Oximeter demonstrates clinically relevant differentiation in the cases of oxygenated and deoxygenated tissue. Therefore, the proposed and cleared devices are substantially equivalent.