ViOptix, Inc.
% Valerie Defiesta-Ng
Executive Director, Regulatory Affairs
Veranex, Inc.
5420 Wade Park Blvd
Suite 204
Raleigh, North Carolina 27607

Re: K250519
Trade/Device Name: Lap.Ox™ Laparoscopic Tissue Oximeter
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: MUD
Dated: February 21, 2025
Received: February 21, 2025

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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

Digitally signed by TANISHA L. HITHE -S
Date: 2025.06.26 15:40:33 -04'00'

Tanisha Hithe
Assistant Director
DHT4A: Division of General Surgery Devices
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K250519

Device Name
Lap.Ox™ Laparoscopic Tissue Oximeter

Indications for Use *(Describe)*
The Lap.Ox™ Laparoscopic Tissue Oximeter is intended to estimate the percent oxygen saturation (StO2) in a volume of tissue, including bowel tissue, during laparoscopy.
The Lap.Ox™ Laparoscopic Tissue Oximeter is indicated for use in monitoring patients during circulatory or perfusion assessment during laparoscopy.
The Lap.Ox™ Laparoscopic Tissue Oximeter is intended to be used by physicians, surgeons, nurses, or other skilled users in a medical environment.
The Lap.Ox™ Laparoscopic 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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K250519 - 510k Summary

Contact Details (21 CFR 807.92(a)(1))

Applicant Name	ViOptix, Inc.
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Correspondent Contact	Ms. Valerie Defiesta-Ng
Correspondent Contact Email	valerie.defiesta-ng@veranex.com
Date Prepared	May 30, 2025

Device Name (21 CFR 807.92(a)(2))

Device Trade Name	Lap.Ox™ Laparoscopic Tissue Oximeter
Common Name	Oximeter
Classification Name	Oximeter, Tissue Saturation
Regulation Number	870.2700
Product Code(s)	MUD

Legally Marketed Predicate Devices (21 CFR 807.92(a)(3))

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K233488	Intra.Ox Handheld Tissue Oximeter	MUD

Device Description Summary (21 CFR 807.92(a)(4))

The proposed Lap.Ox™ Laparoscopic Tissue Oximeter ("Lap.Ox" or "Device") is a cordless, battery-powered device that estimates the percent oxygen saturation (StO2) in a volume of tissue, including bowel tissue. The device includes two components:

- a Reusable Main Unit that shows a digital readout of percent oxygen saturation (StO2) when the system is in contact with tissue (also denoted as "main unit" or "durable"); and
- a Disposable Kit that contains two AA batteries and a sterile single-use disposable consisting of sources, detectors, a laparoscopic tube, and a sheath that is placed around the Reusable Main Unit (denoted as "Disposable").

The Device uses spatially-resolved optical measurements at three wavelengths. The Device displays the StO2 estimate on the built-in screen. The Device is constructed from biocompatible materials that can tolerate bodily fluids. The basic principle of operation of the Lap.Ox Laparoscopic Tissue Oximeter is spectrophotometric oximetry which entails utilizing red and near-infrared light to measure the color of blood and determine an oxygen saturation value.

Intended Use/Indications for Use (21 CFR 807.92(a)(5))

The Lap.Ox™ Laparoscopic Tissue Oximeter is intended to estimate the percent oxygen saturation (StO2) in a volume of tissue, including bowel tissue, during laparoscopy.

The Lap.Ox™ Laparoscopic Tissue Oximeter is indicated for use in monitoring patients during circulatory or perfusion assessment during laparoscopy.

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

The Lap.Ox™ Laparoscopic Tissue Oximeter should only be used on adult patients.

Indications for Use Comparison (21 CFR 807.92(a)(5))

The Lap.Ox Laparoscopic Tissue Oximeter (proposed device) is intended to estimate the percent oxygen saturation (StO2) in a volume of tissue, including bowel tissue, and it is operated by positioning the sensor face, which is located at the distal tip of the laparoscopic tube, through the laparoscopic port on the area of tissue that is to be measured, whereas the Intra.Ox 2.0 Handheld Tissue Oximeter (predicate device) is intended to be used non-invasively to estimate the percent oxygen saturation (StO2) in a volume of tissue, including bowel tissue. The intended use of estimating the StO2 in a volume of tissue, including bowel tissue, is the same for both the proposed and predicate devices. Both proposed and predicate devices are indicated for use in monitoring patients during circulatory or perfusion assessments with the only difference of the proposed device being used laparoscopically versus the predicate device being used non-invasively. The differences in physical design were thoroughly tested by ViOptix. In addition, both proposed and predicate devices have the same intended users, both devices are intended to be used by physicians, surgeons, nurses, or other skilled users in a medical environment. Also, both devices have the same intended patient population, where both devices should only be used on adult patients.

The verification and validation studies demonstrated that Lap.Ox performs as intended and that the difference in physical design and Indications for Use do not raise different questions of safety or effectiveness, and therefore, the proposed and predicate devices are substantially equivalent with regard to the Indications for Use.

Technological Comparison (21 CFR 807.92(a)(6))

The proposed Lap.Ox Laparoscopic Tissue Oximeter is similar to the predicate device with respect to safety and technological characteristics. Both Lap.Ox Laparoscopic Tissue Oximeter (proposed device) and Intra.Ox 2.0 Handheld Tissue Oximeter (predicate device) estimate percent oxygen saturation (StO2) and display the StO2 value on a built-in screen. Both devices are cordless, battery-powered and made from biocompatible materials that can tolerate bodily fluids and disinfectants. Each device includes a Reusable Main Unit and a Disposable Kit (with a Sheath and Batteries). The physical design for both devices are similar, both the predicate device and proposed device are ergonomic hand-held design for range of hand sizes for ambidextrous use, with the proposed device being different where it is operated by positioning the sensor face, which is located at the distal tip of the laparoscopic tube, through the laparoscopic port on the area of tissue. The devices have the same principle of operation, both devices use Spectrophotometric oximetry relying on near-infrared light and LED chips of similar wavelengths. There are three wavelengths used for proposed device; 760nm, 810nm, and

840nm, whereas the predicate device uses five wavelengths; 730nm, 760nm, 810nm, 845nm, 895nm. To demonstrate that the differences between the proposed Lap.Ox and the predicate device do not raise different questions of safety and effectiveness, ViOptix performed comprehensive non-clinical performance testing and clinical testing. The bench testing data from the proposed device with three wavelengths (760nm, 810nm, and 840nm), demonstrates the required performance compared to the predicate device with five wavelengths (730nm, 760nm, 810nm, 845nm, 895nm). All the testing demonstrated substantial equivalence to the predicate device, where applicable, reasonable StO2 performance on representative clinical samples, and conformance to the relevant regulatory standards.

Non-Clinical and/or Clinical Tests Summary & Conclusions (21 CFR 807.92(b))

ViOptix has conducted all necessary testing to demonstrate that the proposed device meets all performance specifications necessary to achieve its intended use and Indications for Use and to provide evidence of substantial equivalence to the predicate device. The specific testing included:

Performance Testing – Bench

- Design Verification in accordance with 21CFR§820.30 Design controls and ISO 13485:2016, *Medical devices — Quality management systems — Requirements for regulatory purposes*
- Risk Management in accordance with 14971:2019, *Medical devices — Application of risk management to medical devices*
- Power Certification: IEC 62133-2:2017, *Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems*
- RoHS2 Compliance for Disposable Kit in accordance with Directive 2011/65/EU *of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment*
- ANSI/AAMI HE75:2009 (R2018), *Human factors engineering - Design of medical devices* (19.3.5.1; 21.4.9; 21.4.6.3 and 22.4.5).
- ANSI/IES RP-27.1-2015, *Recommended Practice for Photobiological Safety for Lamps and Lamp Systems –General Requirements*

Software Verification and Validation

- IEC 62304:2006, Medical device software — Software life cycle processes
- FDA Guidance Document entitled, "*Content of Premarket Submissions for Device Software Functions*," issued June 14, 2023

Cybersecurity Testing

- FDA Guidance Document entitled, "*Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions*," issued 26 September 2023

Electrical Safety and Electromagnetic Compatibility Testing

- IEC 60601-1-2:2014+A1:2020, *Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests*.
- CISPR 11:2015+A1:2016+A2:2019, *Industrial, scientific and medical equipment - Radio-frequency disturbance characteristics - Limits and methods of measurement*
- IEC 60601-1:2005/AMD1:2012/AMD2:2020, *Medical electrical equipment - Part 1: General requirements for basic safety and essential performance*

Biocompatibility Testing

- ISO 10993-1, *Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*
- Cytotoxicity, L929 - Minimum Essential Medium Elution Test (ISO 10993-5, *Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity*)
- Sensitization, Guinea Pig Maximization Test (ISO 10993-10, *Biological evaluation of medical devices Part 10: Tests for skin sensitization*
- Intracutaneous Reactivity Test (ISO 10993-23, Biological evaluation of medical devices Part 23: Tests for irritation)
- Acute Systemic Toxicity (ISO 10993-11, Biological evaluation of medical devices Part 11: Tests for systemic toxicity)
- Material-Mediated Pyrogen Test (ISO 10993-11, Biological evaluation of medical devices Part 11: Tests for systemic toxicity)

Cleaning Validation and Low-Level Disinfection Validation

- AAMI TIR ST98:2022, *Cleaning validation of health care products – Requirements for development and validation of a cleaning process for medical devices.*
- AAMI TIR 12:2020, *Designing, testing, and labeling medical devices intended for processing by health care facilities: A guide for device manufacturers*
- FDA Guidance Document entitled, "*Reprocessing Medical Devices in Health Care Setting Validation Methods and Labeling,*" issued March 17, 2015
- ISO 17664-1:2021, *Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices. Part 1: Critical and semi-critical medical devices*
- U.S. FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Sterilization Validation Testing

- ISO 11135:2014/AMD 1:2018, *Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices*
- ISO 10993-7:2008/AMD 1:2019, *Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals*
- ISO 11737-1:2018/Amd1:2021, *Sterilization of health care products – Microbiological methods – Part 1: Determination of the population of microorganisms on products*

Shelf-Life and Packaging Validation Testing

- Gross Leak Detection (Bubble): ASTM F2096-11, Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)
- Seal Strength (Peel): ASTM F88/F88M-23, *Standard Test Method for Seal Strength of Flexible Barrier Materials*
- Accelerated Aging: ASTM F1980-21, *Standard Guide for Accelerated Aging of Sterile Barrier Systems and Medical Devices*
- Transportation: ISTA 3A-2018, *General Simulation Performance Test Procedure for Parcel Delivery System Shipment 70 kg (150 lb) or Less.*
- ASTM D4332-22, *Standard Practice for Conditioning Containers, Packages, or Packaging Components for Testing*

These tests confirmed that any technological differences between the proposed device and the predicate device do not raise different questions of safety or effectiveness. The results of the tests support that the proposed device is at least as safe and as effective as the predicate devices for the same intended use.

ViOptix conducted a clinical study in accordance with 21 CFR Parts 50, 56 and 812 to compare the proposed device to the predicate device. The results demonstrated that the performance of the Lap.Ox Laparoscopic Tissue Oximeter, on human subjects, is comparable to the predicate device.

The tests demonstrated that the proposed device functions as intended for its proposed intended use and Indications for Use. These results further support that the proposed device performs at least as well as the predicate device for the same intended use and confirm that any technological differences do not raise different questions of safety or effectiveness.