**Attachment B**

JUL 0 1 2014

**5. 510(k) Summary or 510(k) Statement**

510(k) SUMMARY

| | |
|---|---|
| 510(k) Owner | ViOptix Inc.<br>47224 Mission Falls Ct.<br>Fremont, CA 94539<br>TEL: 510.226.5860<br>FAX: 510.226.5864 |
| Contact person | Greg Holland<br>Regulatory Consultant to ViOptix Inc.<br>Regulatory Specialists, Inc.<br>3722 Ave. Sausalito<br>Irvine, CA 92606<br>TEL: 949.262-0411<br>FAX: 949.552.2821<br>EMAIL: greg@regulatoryspecialists.com |
| Date summary was prepared | June 4, 2014 |
| Common Name | Oximeter |
| Trade Name | ODISsey Tissue Oximeter |
| Classification Name | Oximeter, Tissue Saturation |
| Regulation | 870.2700 |
| Class | II |
| Panel | Cardiovascular |
| Product Code | MUD |
| Predicate | K042657, ViOptix ODISsey Tissue Oximeter |

Description

The ODISsey Tissue Oximeter is an optically based device that non-invasively estimates the percent oxygen saturation ($StO_2$) in a volume of tissue underneath the sensor.

Intended Use

The ODISsey Tissue Oximeter is intended for use as an estimate of the percent oxygen saturation ($StO_2$).

Indications for Use

The ViOptix ODISsey Tissue Oximeter is intended to non-invasively estimate the percent oxygen saturation ($StO_2$) in a volume of tissue. This is performed in medical environments including physician offices, hospitals, ambulatory care and Emergency Medical Services.

The ODISsey Tissue Oximeter is indicated for use in monitoring patients during circulatory or perfusion examinations of skeletal muscle or when there is a suspicion of compromised circulation.

Technological Characteristics

The technological characteristic of the ODISsey Tissue Oximeter remain unchanged from the predicate K042657. This Special 510(k) is being submitted for a change in patient contact materials and design.

The T.Ox™ Tissue Oximeter is a lightweight and portable, AC power–operated, unit with a lithium-ion battery backup that non-invasively estimates the percent oxygen saturation (StO2%) in a volume of tissue underneath the sensor. The console has a color LCD display monitor, a standard one sampling channel (with a two-channel option), and up to two fiber optic sensors. It has adjustable audible and visual alarms for:

· StO2 low and high alarm limits
· Low battery

The T.Ox™ Tissue Oximeter has visual alarms.

The T.Ox™ Tissue Oximeter consists of three parts:

· Small computer console display module
· AC power cord
· Fiber optic sensor(s)

If the console is using two channels, both channels can be used at the same time. Each channel samples and displays data independently of the other channel. Each channel can accommodate one sensor.

Changes in the ViOptix ODISsey Tissue Oximeter from K042657.

| | **Original K042657** | **New Design** |
|---|---|---|
| Sensor Use | Reusable | Single Use Only |
| Sterility | Sensor non sterile | Entire Sensor is sterilized |
| Packaging | Non Sterile package | Entire Sensor is in sterile package |
| Cable Cover | PVC for sheath | MD-565 a Thermoplastic Elastomer for sheath |
| Sensor Design | Can be laid flat and optionally taped in place | No Change |
| Sensor Material | Metal/Epoxy | No Change |
| Console | Electrical and Laser control system | No Change |
| Software | Control of ViOptix ODISsey Tissue | No Change |

| | Oximeter | |
|---|---|---|
| Wavelengths | Laser Light | No Change |
| Laser Power | Amount of Laser power | No Change |

Conclusions from non-clinical performance data

After performing non-clinical performance studies, Biocompatibility to ISO 10993, Packaging Validation, Sterilization Validations and Aging Sudies, the data shows that the ODISsey Tissue Oximeter is substantially equivalent to the predicate as an estimate the percent oxygen saturation ($StO_2$) in a volume of tissue.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

July 1, 2014

Vioptix, Inc.
Mark Lonsinger
Greg Holland, Regulatory Specialists Inc.
3722 Ave. Sausalito
Irvine, California 92606

Re: K141234
Trade/Device Name: Odissey Tissue Oximeter
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter, Tissue Saturation
Regulatory Class: Class II
Product Code: MUD
Dated: May 23, 2014
Received: May 27, 2014

Dear Greg Holland,

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.

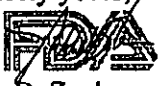
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply

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 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 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 yours,



forBram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

**4. Indications for Use Statement**

Indications for Use

510(k) Number (if known): _____

Device Name: ODISsey Tissue Oximeter

Indications for Use:

The ViOptix ODISsey Tissue Oximeter is intended to non-invasively estimate the percent oxygen saturation (StO2) in a volume of tissue. This is performed in medical environments including physician offices, hospitals, ambulatory care and Emergency Medical Services.

The ODISsey Tissue Oximeter is indicated for use in monitoring patients during circulatory or perfusion examinations of skeletal muscle or when there is a suspicion of compromised circulation.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

FDA Date: 2014.07.01 11:44:32 -04'00'

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