JAN 1 0 2005

K042657 p.1/3

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SUMMARY

Submitter's name: Address:	ViOptix, Inc. 44061-B Old Warms Springs Blvd. Fremont, CA 94538
Phone: Fax number:	510-226-5860 510-226-5864
Name of contact person:	Greg Holland Regulatory Specialists, Inc 3722 Ave. Sausalito Irvine, CA 92606 Phone: 949-262-0411
Date the summary was prepared:	September 27, 2004
Name of the device: Trade or proprietary name: Common or usual name: Classification name:	ViOptix ODISsey Tissue Oximeter Tissue Oximeter Tissue Spectrometer Oximeter

The legally marketed device to which we are claiming equivalence [807.92(a)(3)]:

K012759 and K023938, InSpectra Tissue Spectrometer System, Model 325, manufactured by Hutchinson Technology Inc. and the Biospectrometer NB Oximeter Model 1111 K963903, also manufactured by Hutchinson Technology.

Description of the device:

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.

Indications:

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.

Summary of the technological characteristics of our device compared to the predicate device:

Technological Characteristics

The technological characteristics of the ODISsey ™ Tissue Oximeter, Model Oxy-2 are similar to those of the cited predicate devices, as well as similar devices based on near-infrared technology. These devices are equivalent in terms of design, functionality, principles of operation, performance specifications and indications for use. When compared to the predicate device, ODISsey ™ Tissue Oximeter, Model Oxy-2 does not raise new technological issues.

Indications for Use

Oximeters and perfusion monitors are used to measure oxygen saturation in the arteries or tissues, or to assess the amount of oxygen delivered to the tissues. Substantial equivalence for the ODISsey ™ Tissue Oximeter, Model Oxy-2 is supported by the predicate devices with identical indications for use.

Performance Testing

Bench testing, biocompatibility testing, and animal studies, were performed to demonstrate the product functions as intended. The ODISsey ™ Tissue Oximeter, Model Oxy-2 is designed to comply with the requirements of electrical safety, laser safety, and electromagnetic compatibility requirements.

Animal Testing

The ViOptix ODISsey™ Tissue Oximeter product performance was evaluated against a "gold standard" CO-Oximeter and a FDA cleared predicate device from Hutchinson. Testing was performed by measuring tissue oxygen saturation (StO_2) on three dog limbs surgically removed and perfused with an extracorporeal blood circulation system. Oxygen perfusion was controlled and monitored by

a Radiometer OSM3™ Hemoximeter (CO-Oximeter). The ViOptix StO_2 values were then compared with those from the CO-Oximeter and a Hutchinson's InSpectra™ Tissue Spectrometer. These results show excellent correlation with both the "gold standard" and the predicate device.

CONCLUSION

Based on the design, technology, performance and functional testing, intended use, and clinical evaluation, the ODISsey ™ Tissue Oximeter, Model Oxy-2 is substantially equivalent to the devices currently marketed under the Federal Food, Drug and Cosmetic Act. The ODISsey ™ Tissue Oximeter, Model Oxy-2 raises no new issues of safety or effectiveness. Therefore, safety and effectiveness are reasonably assured, and substantial equivalence is supported, justifying 510(k) clearance of the ODISsey ™ Tissue Oximeter, Model Oxy-2.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 10 2005

ViOptix, Inc.
c/o Mr. Greg Holland
Regulatory Specialists, Inc.
3722 Ave. Sausalito
Irvine, CA 92606

Re: K042657
Trade Name: ODISsey Tissue Oximeter
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II (two)
Product Code: MUD
Dated: December 27, 2004
Received: December 28, 2004

Dear Mr. 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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

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

Enclosure

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Indications for Use Statement

510(k) Number (if known): K042657

Device Name: ViOptix ODISsey Tissue Oximeter

Indications For Use:

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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 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K042657

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