K093520

JAN – 5 2010

Executive Summary

This executive summary has been prepared in accordance with 21 CFR 807.87(h) and the 510(k) has been prepared in accordance with 21 CFR 807.92

Submitter	Michelson Diagnostics Ltd 11A Grays Farm Production Village Grays Farm Road Orpington Kent BR5 3BD	
Contact Person	Name:	Martin Johns
	Job Title:	Operations Director
	Address:	11A Grays Farm Production Village Grays Farm Road Orpington Kent BR5 3BD United Kingdom
	Telephone number:	00 1 44 208 308 1695
	Fax number:	00 1 44 121 275 6237
Date Summary Prepared	November 11, 2009	
Device Trade Name	VivoSight Topical OCT System	
Device Common Name	Multi-Beam Optical Coherence Tomography (OCT) scanner	
Device Classification	II	
Legally Marketed devices to which the device is substantially equivalent	Imalux OCT Imaging System	
Description of the Device	Multi-Beam Optical Coherence Tomography (OCT) tissue imaging system	
Intended Use of the Device	The intended use of the Michelson Diagnostics VivoSight Topical OCT System: Intended to be used as an imaging tool in the evaluation of external human tissue microstructure by providing two-dimensional, cross-sectional, real-time depth visualization This is the same as the predicate device with the addition that it is for external tissue only	

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

JAN - 5 2010

Michelson Diagnostics Ltd.
% Mr. Martin Johns
Operations Director
11A Grays Farm Production Village
Grays Farm Road, Orpington
Kent BR5 3BD, United Kingdom

Re: K093520
Trade/Device Name: VivoSight Topical OCT System
Regulation Number: 21 CFR 892-1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: Class II
Product Code: NQQ
Dated: December 16, 2009
Received: December 22, 2009

Dear Mr. Johns:

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 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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/cdrh/mdr/ 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K093520

Device Name: VivoSight Topical OCT System
(A Multi-Beam Optical Coherence Tomography (OCT) scanner)

Indications for Use:

VivoSight is a Multi-Beam Optical Coherence Tomography (OCT) system indicated for use in the two-dimensional, cross-sectional, real-time imaging of external tissues of the human body.

Prescription Use **YES** (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use **NO** (Part 21 CFR 801 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 Surgical, Orthopedic,
and Restorative Devices

510(k) Number K093520