 DEC 1 2010

510(k) Summary per 21 CFR 807.92 510(k) number: K102599

A. 510(k) owner's name, address, phone and fax numbers, name of contact person, and date the summary was prepared [21 CFR 807.92(a)(1)]

Company Name:	Tomophase Corporation
Company Address:	1 North Avenue, Burlington, MA 01803
Company Phone:	(781) 229-5700
Company Fax:	(781) 229-5737
Contact Name & Title:	Derek Beaupre, Regulatory & Quality Consultant
Contact Email:	Derek@BeaupreConsulting.com
Contact Phone:	(603) 264-3831
Date Prepared:	August 31, 2010

B. Device Name [21 CFR 807.92(a)(2)]

Trade Name:	Tomophase OCTIS
Common Name:	Optical Coherence Tomography Imaging System
Device Classification Name:	System, Imaging, Optical Coherence Tomography (OCT)
Regulation Number:	892.1560
Product Code:	NQQ
Review Panel:	General & Plastic Surgery
Device Class:	II

C. Legally marketed predicate device for substantial equivalence [21 CFR 807.92(a)(3)]

Substantial equivalence is being claimed with the following legally marketed predicate device:	Imalux OCT Imaging System
Predicate device 510(k) number:	K033783

D. Description of the device [21 CFR 807.92(a)(4)]

The Tomophase OCTIS is an imaging tool for the evaluation of human tissue microstructure by providing two-dimensional, cross-sectional, real-time depth visualization. The system consists of an Imaging Console and a detachable Probe.

The Imaging Console contains optical and electrical components to utilize NIR light to create high resolution real-time images; and has a user interface for acquiring, displaying, saving and reporting the images.

The Probe is a single-use, sterile device consisting of a sealed sheath and a flexible fiber optic mechanism.

E. Intended use of the device [21 CFR 807.92(a)(5)]

The Tomophase OCTIS (Optical Coherence Tomography Imaging System) is indicated for use as an imaging tool in the evaluation of human tissue microstructure by providing two-dimensional, cross-sectional, real-time depth visualization.

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F. Technological characteristics of the device as compared to predicate device [21 CFR 807.92(a)(6)]

Both the new Tomophase OCTIS and the predicate Imalux OCT utilize Optical Coherence Technology to create high resolution cross-sectional real-time images of tissue microstructure. Both devices also use low coherence interferometry to measure in-depth backscattering profiles to construct the images.

A summary of the technological characteristics is provided the following table:

Criteria	Imalux OCT Imaging System	Tomophase OCTIS
Measurement Technique	Optical Coherence Tomography (OCT)	Optical Coherence Tomography (OCT)
Optical Technology	Uses NIR (near infrared light) to create high resolution real-time images.	Uses NIR (near infrared light) to create high resolution real-time images.
Wavelength [NIR Range: 700-1400 nm]	960 – 990 nm	1250 – 1360 nm
Optical Source	Super Luminescent Diode (SLD)	Swept Source Laser
Laser Safety Class	3R	3R
Optical Radiation Emission Safety	Safe for indicated use (8% of Maximum Permissible Exposure)	Safe for indicated use (<10% of Maximum Permissible Exposure)

G. Non-clinical performance data [21 CFR 807.92(b)(1)]

Safety testing, bench testing, and animal testing were used to evaluate the safety and performance of the Tomophase OCTIS. These tests include the following

Safety Testing	Recognized Standard
Risk Management	ISO 14971
Medical Electrical Equipment	IEC 60601-1
Electrical Safety	IEC 60601-1-1
Electromagnetic Compatibility	IEC 60601-1-2
Safety of Endoscopic Equipment	IEC 60601-2-18
Laser Safety	IEC 60825-1
Biocompatibility	ISO 10993-1
Sterilization Validation	AAMI/ANSI/ISO 11135-1
Ethylene Oxide Residuals	ISO 10993-7
Sterile Package Integrity	ISO 11607-1, ISO 11607-2, ASTM F88, and ASTM F1929

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Bench Testing	**Tomophase Documents**
OCTIS Optical Radiation Safety Analysis	Tomophase Doc # TES-001
Digitizer Qualification	Tomophase Doc # RPT-001
Optical Connection Tests	Tomophase Doc # RPT-002
Outer Sheath Seal Tests	Tomophase Doc # RPT-003
Animal Testing	**Tomophase Document**
Beth Israel Deaconess Medical Center Report on OCTIS Procedure with Canine TBM Model	Tomophase Report dated August 6, 2010

H. Clinical performance data [21 CFR 807.92(b)(2)]

This section is not applicable because Tomophase Corporation is not including any clinical performance data with this 510(k) submission.

I. Conclusions from performance data [21 CFR 807.92(b)(3)]

Performance data from the tests listed in section G above show that the Tomophase OCTIS meets the design criteria, the performance objectives, and the user requirements.

The Tomophase OCTIS is a safe and effective device for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

DEC 1 2010

Tomophase Corporation
% Beaupre Consulting
Mr. Derek Beaupre
14 Burgundy Drive
Hampton, New Hampshire 03842

Re: K102599
Trade/Device Name: Tomophase OCTIS, Model 100002
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: Class II
Product Code: NQQ
Dated: November 02, 2010
Received: November 12, 2010

Dear Mr. Beaupre:

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 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/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 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/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

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

DEC 1 2010

510(k) Number (if known): K102599

Device Name: Tomophase OCTIS (Optical Coherence Tomography Imaging System), Model 100002

Indications For Use:

The Tomophase OCTIS (Optical Coherence Tomography Imaging System) is indicated for use as an imaging tool in the evaluation of human tissue microstructure by providing two-dimensional, cross-sectional, real-time depth visualization.

Prescription Use ✓ 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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark R Ogden for mxm
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K102599