510(k) SUMMARY

This summary is being submitted in accordance with 21 CFR 807.92.

A. Submitter's name, address, telephone number, initial importer, contact person

Submitter's Name:	Imalux Corporation
Address:	1771 East 30th Street
Address:	Cleveland, OH 44114
Official Contact:	Stephanie A. S. Harrington
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B. Device Name, Common Name

1. Common/Usual Name

Optical Coherence Tomography Scanner

2. Device Name

Imalux OCT Imaging System

3. Classification Name

Name	Classification Regulation	Product Code	Class
Ultrasonic pulsed echo imaging system	892.1560	IYO	II

C. Identification of the predicate or legally marketed device

Device Name	510(k) Number
Humphrey Optical Coherence Tomography (OCT) Scanner	K944523

D. Device Description

1. Summary

The Imalux OCT (Optical Coherence Tomography) Imaging System utilizes near infrared (NIR) light to create high spatial resolution, real-time images of human tissues. The Imalux OCT Imaging System consists of an Imaging Console and a detachable, flexible fiberoptic Probe. The Imaging Console consists of internal optical and electrical components and a user interface system. The user interface system includes a keyboard, display, and standard Ethernet and USB ports for image data transfer.

As various tissue structural elements absorb, reflect, and scatter light differently, NIR light that is backscattered from the tissue is collected and analyzed to present an image of the tissue microstructure. By analyzing backscattered intensity as a function of tissue depth, over a lateral surface, a 2-dimensional image is constructed.

At any one lateral position, the in-depth OCT image is analogous to an ultrasound A-scan in that it presents backscattering intensity as a function of depth. By combining the in-depth scanning with lateral movement of the Probe beam, a 2-dimensional image is created that is analogous to that of ultrasound B-scan, except that OCT uses light in lieu of sound waves. By using light instead of sound, the Imalux OCT Imaging System can achieve higher spatial resolution, but to a more shallow imaging depth, than ultrasound imaging since light is more readily attenuated in the tissue.

2. Design

The Scanner contains optical and electrical components, including a super luminescent diode (SLD) light source. The NIR light is directed from the Scanner through the Probe's optical fiber to the patient's tissue. The optical light is backscattered from the patient's tissue, collected by the Probe's fiber, and, combined with an internal reference signal, to produce a high spatial resolution image of the superficial tissue microstructure. By using a small lateral scanning mechanism contained within the probe, the optical beam scans laterally across the tissue surface while simultaneously acquiring an in-depth profile at each lateral position. By combining in-depth and lateral scanning, the Imalux OCT Imaging System produces a two-dimensional cross-sectional image of the tissue microstructure.

The Imaging Console has a user interface for acquiring, displaying, and reporting images. Image data is stored onto the system and can be exported via Ethernet or USB data ports on the console.

3. Materials

The external materials of the Probe distal tip are commonly used medical device materials and have been evaluated for biocompatibility. This evaluation, supported with biocompatibility testing, has demonstrated that these materials are safe for the Probe's intended use.

E. Intended Use

The Imalux OCT (Optical Coherence Tomography) Imaging System is intended to be used as an imaging tool in the evaluation of human tissue microstructure by providing two-dimensional, cross-sectional, real-time depth visualization.

While the Humphrey's indication is for ocular use, imaging of sensitive eye tissue, the Imalux OCT Imaging System is indicated for use on tissue types such as skin and mucosal membranes. While the indications are different, the indications for the Imalux OCT device and the Humphrey OCT device are both within the same intended use and a comparison of their respective technologies and functional characteristics shows that the Imalux device is at least as safe and effective as the Humphrey device for this intended use.

F. Safety & Performance

To assure the safety of the device, the System has been tested to and complies with the standards listed below:

EN / IEC 60601-1
EN / IEC 60601-1-2
EN / IEC 60825-1
AAMI / ANSI / ISO 10993-1
AAMI / ANSI ST35

The Imalux OCT Imaging System is substantially equivalent to the Humphrey OCT Scanner as both devices employ the same technology, Optical Coherence Tomography, and have the same intended use of revealing tissue structural information by providing two-dimensional, cross-sectional, real-time depth visualization.

Both the Imalux OCT Imaging System and the Humphrey OCT Scanner employ NIR light that is transported through a fiberoptic connection. The Imalux device uses a detachable, fiberoptic Probe that facilitates the transport of NIR light between the Imaging Console and the patient tissue; whereas, the Humphrey OCT Scanner has a fiberoptic imaging head that is connected to the console. By using a detachable, fiberoptic Probe, the

Imalux device can acquire images from different target tissues and facilitate reprocessing; whereas, the Humphrey device requires that the patient be positioned in close proximity to the imaging head, a design which is compatible for the device's indication for scanning ocular tissue. The Imalux device permits tissue image sampling, consistent with its indication for use, while employing the same fundamental OCT technological characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 1 2004

Ms. Stephanie A.S. Harrington
Vice President, Regulatory
and Clinical Affairs
Imalux Corporation
1771 East 30th Street
Cleveland, Ohio 44114

Re: K033783
Trade/Device Name: Imalux OCT Imaging System
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: NQQ
Dated: December 3, 2003
Received: December 4, 2003

Dear Ms. Harrington:

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 (301) 594-4659. 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,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

4 INDICATIONS FOR USE

510(k) Number (if known): K033783

Device Name: Imalux OCT Imaging System

Indications For Use:

The Imalux OCT (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 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N. Melkerson

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K033783