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K042894

3 510(k) SUMMARY

NOV 19 2004

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
Title:	Vice President, Regulatory & Clinical Affairs
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B. Device Name, Common Name

1. Common/Usual Name

Optical Coherence Tomography (OCT) Imaging System

2. Device Name

Imalux Niris™ Imaging System

3. Classification Name

Name	Classification Regulation	Product Code	Class
System, Imaging, Optical Coherence Tomography (OCT)	892.1560	NQQ	II

C. Identification of the predicate or legally marketed device

Device Name	510(k) Number
Imalux OCT Imaging System	K033783

D. Device Description

The Imalux Niris Imaging System utilizes near infrared (NIR) light to create high spatial resolution, real-time images of human tissue microstructure. The Niris 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 Niris Imaging Console contains optical and electrical components, including a super luminescent diode (SLD) light source. The NIR light is directed from the Console 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 a reference, to produce a high spatial resolution image of the tissue microstructure. By using a small lateral scanning mechanism contained within the Probe, the optical beam scans laterally across the tissue surface while simultaneously

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acquiring an in-depth profile at each lateral position. By combining in-depth and lateral scanning, the Niris 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.

E. Intended Use

The Imalux Niris 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.

F. Comparison to Predicate Device:

The Niris Imaging System is substantially equivalent in its intended use, technologies, principle of operation, and functionality to the Imalux OCT Imaging System, cleared under 510(k) premarket notification number K033783. It has the same technological characteristics, key safety and performance features, physical design, construction, and has the same intended uses and operating modes as the predicate device.

Both Systems include an Imaging Console and a detachable, reusable Probe. Within the Console, both System designs are based on the principles of Optical Coherence Tomography, which utilizes low coherence interferometry. In addition, both Systems use Near Infrared (NIR) light, albeit at slightly different central wavelengths. A modification in the optical topology has enabled Probes of different lengths to be used with the same Console, without impacting the performance specifications. Image performance specifications have remained unchanged. The Probe distal design is the same for both devices; however, the proximal end connector to the console has been integrated from two separate connectors into one for ease of use. Minor software enhancements, such as image scrolling, have been added to facilitate ease-of-use.

These design modifications have been verified and validated to fulfill the performance requirements of the device. In addition, the device has been tested for compliance to applicable safety testing standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 19 2004

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

Re: K042894
Trade/Device Name: Imalux Niris™ Imaging System
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: NQQ
Dated: October 18, 2004
Received: October 20, 2004

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 (240) 276-0115. 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 Miriam C. Provost

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): K042894 1 of 1

Device Name: Imalux Niris™ Imaging System

Indications For Use:

The Imalux Niris 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)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K042894

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