K041077

JUN 2 5 2004

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

1. Common/Usual Name

Probe Sheath

2. Device Name

Imalux OCT Probe Sheath

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
CIVCO Medical Instruments Synthetic Polyisoprene Ultrasound Transducer Cover	K013721
Vision-Sciences Slide-On™ EndoSheath® System for use with Flexible ENT Scopes	K990354

D. Device Description

1. Summary

The Imalux OCT (Optical Coherence Tomography) Probe Sheaths (Probe Sheaths) are sterile, single-use, protective sheaths for use with the Imalux OCT Imaging System. The sheaths are provided to fit the Imalux OCT Imaging System probe geometry and to help to prevent the transfer of microorganisms, body fluids, and material to the patient and healthcare worker during reuse of the Probe.

The Probe Sheath does not impair the imaging performance of the Imalux OCT Imaging System. Adequate coupling between the Probe Sheath and the probe's distal end can be achieved without the use of an additional medium, such as gel, due to the pliability of the membrane window material.

2. Design

The Probe Sheath is constructed of rigid tubing with a flexible end cap membrane window at one end and with a plastic handle at the other end. The probe is inserted into the tubing at the handle and fed through the tubing until the probe's distal tip is flush with the Probe Sheath's membrane window. The handle includes a lock nut to secure the probe in place. The Probe Sheath is provided in various dimensional configurations necessary to accommodate the probe as well as to assist the user in probe positioning.

Probe Sheaths are provided as sterile, single-use sheaths, individually packaged in Tyvek/Mylar pouches.

3. Materials

The Probe Sheath is constructed of commonly used medical device materials and has been evaluated for biocompatibility. This evaluation has demonstrated that the Probe Sheath is safe for its intended use.

The intended use and indications for use place the Probe Sheath in the device body contact categories as follows:

a. surface devices, intact skin / mucosal membranes / breached surfaces, limited contact duration (<24 hours)
b. external communicating devices, tissue communicating, limited contact duration (<24 hours)

E. Intended Use

The Imalux OCT (Optical Coherence Tomography) Probe Sheath is a sterile, single-use, protective sheath for use as an accessory with the Imalux OCT Imaging System. The Probe Sheath is intended to serve as a microbial barrier between the probe and the patient's tissue, helping to prevent the transfer of microorganisms, body fluids, and particulate material to the patient and healthcare worker during reuse of the probe.

The Imalux OCT Probe Sheath is substantially equivalent in safety and performance to the CIVCO Synthetic Polyisoprene Ultrasound Transducer Cover and to the Vision-Sciences EndoSheaths (Section C).

F. Safety & Performance

To assure the safety of the device, the Probe Sheath was tested for biocompatibility per AAMI/ANSI/ISO 10993 for cytotoxicity, acute systemic toxicity, intracuteanous reactivity, sensitization, and ethylene oxide sterilization residuals. Testing was performed in accordance with ISO 10993-Part 1 Biological Evaluation of Medical Devices, FDA Blue Book Memorandum #G95-1, and FDA-Good Laboratory Practices 21 CFR Part 58 (GLP). These tests demonstrated that the Probe Sheath device is non-toxic, non-irritating, non-sensitizing, and can be safely sterilized with ethylene oxide.

The Probe Sheath was verified for imaging, mechanical, and packaging performance. The Probe Sheath's materials and design have been shown to not impair the optical imaging performance of the Imalux OCT Imaging System. Mechanical verification of the Sheath, such as tensile strength, demonstrated that the Probe Sheath's distal end will withstand normal use.

Microbial barrier testing demonstrated that the Probe Sheath was capable of preventing the transmission of a challenge virus with a diameter of 25-27 nanometers (nm), smaller than most clinically relevant viruses, to a detection limit of less than 5.5×10^{-7} milliliters (mL) of challenge virus suspension.

The Probe Sheath, individually packaged in its Tyvek/Mylar package, was successfully sterilized with 100% ethylene oxide. The sterilization process was designed and verified to provide a sterility assurance level (SAL) of 10^{-6}. In addition, the Tyvek/Mylar package was verified for strength and integrity.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K041077
Trade/Device Name: Imalux OCT Probe Sheath
Regulation Number: 878.4370, 892.1560
Regulation Name: Surgical Drape and Drape Accessories, Ultrasonic Pulsed Echo Imaging System
Regulatory Class: II
Product Code: KKX, NQQ
Dated: May 28, 2004
Received: June 1, 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 (301) 594-4618. 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,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K041077

Device Name: Imalux OCT Probe Sheath

Indications For Use:

The Imalux OCT (Optical Coherence Tomography) Probe Sheath is a sterile, single-use, protective sheath that is used as an accessory with the Imalux OCT Imaging System. The Imalux OCT Probe Sheath is intended to serve as a microbial barrier between the probe and the patient's tissue, helping to prevent the transfer of microorganisms, body fluids, and particulate material to the patient and healthcare worker during reuse of the probe.

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)

Ron Mely
(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices
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