

LMI IRRIGATION CATHETER 510K NOTIFICATION
LUCAS MEDICAL, INC.
1751 S. DOUGLASS ROAD, ANAHEIM CA 92806

K972623
510K APPLICATION
PAGE 1 OF 14

510K SUMMARY

NOV 19 1997

PURPOSE: Pursuant to the Federal Food, Drug, and Cosmetic Act, as amended May 28, 1976, Section 510(k), please consider the attached document as Lucas Medical, Inc.'s notification of intent to introduce the LMI Irrigation Catheter for commercial distribution. The common names for the device are silicone irrigation catheter and irrigation catheter.

MANUFACTURING & STERILIZATION SITES: The manufacturing and packaging facility is: Lucas Medical Inc., 1751 S. Douglass Road, Anaheim CA 92806. The establishment registration number is: 2029386. Sterilization will be performed by Griffith MicroScience (Establishment Registration Number: 2011171) 4900 S. Gilford, Los Angeles CA 90058.

DESCRIPTION: The catheter consists of a stainless steel wire reinforced silicone tube that is end formed to create a rounded leading nose. The proximal end of the catheter consists of a female luer connector and a strain relief that are bonded to the silicone shaft. The distal end of the catheter has four side ports as well as central lumens that provide openings for irrigating fluid. The "DEVICE" is packaged in an EtO breathable tray for protection and then sealed in an EtO breathable pouch. It is EtO sterilized and non-pyrogenic. The "DEVICE" is for Single Use Only and is used only By or On the Order of a Physician.

CLASSIFICATION: The "DEVICE" is a Class II Medical device and has a classification number of 74DXE and is reviewed by the Cardiovascular Review Panel.

LABELING & INTENDED USE : Labeling including the Instructions for Use are included in this submission. The device is intended for intra-operative procedures requiring irrigation in blood vessels, namely arteries and veins.

PRINCIPLE OF OPERATION: Irrigation catheters are generally used in procedures to facilitate the use of irrigating media in either arterial or venous blood vessels, to flush the immediate area of a thrombectomy or embolectomy. The affected blood vessel is accessed surgically proximal to the desired region. The appropriately sized irrigating catheter for the blood vessel is selected. The catheter is inserted into the vessel and advanced distally to the desired region. The irrigating media is then infused into the catheter via a syringe. The catheter is then pulled back toward the venous/arterial incision and removed. Additional irrigating media may be infused by utilizing the same technique.

SUBSTANTIAL EQUIVALENCE: The "DEVICE" is substantially equivalent to the Fogarty Irrigation Catheter and Intimax Irrigating Catheter currently in the market. The materials of construction, methods of construction and the packaging and sterilization of the "DEVICE" are identical to the approved LMI Arterial Bi-Lumen Irrigation Embolectomy Catheter (510k -K955499). The Indicated Use of the Device is substantially equivalent to the Fogarty Irrigation Catheter manufactured by Baxter Healthcare and the Intimax Irrigation Catheter manufactured by Applied Vascular.

Please Address all correspondence and questions to:

Mr. Daniel R. Lucas, President
Lucas Medical, Incorporated
1751 S. Douglass Road
Anaheim CA 92806
Phone: 1-714-938-0233
FAX: 1-714-938-0130



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 19 1997

Mr. Daniel R. Lucas
Lucas Medical, Inc.
1751 S. Douglass Road
Anaheim, California 92806

Re: K972623
LMI Irrigation Catheter
Regulatory Class: II (two)
Product Code: 74 DXE
Dated: October 26, 1997
Received: October 30, 1997

Dear Mr. Lucas:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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.

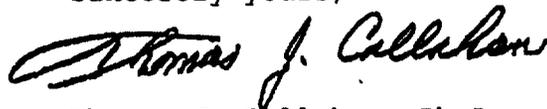
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

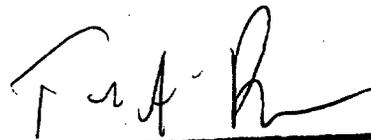


Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

The LMI Irrigation Catheter is intended for intra-operative procedures requiring irrigation in either arterial or venous blood vessels.



(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number _____

K972623