JUL 30 1999

K983802

LMI CAROTID ENDARTERECTOMY SHUNT 510K NOTIFICATION
LUCAS MEDICAL , INC.
1751 S. DOUGLASS ROAD, ANAHEIM CA 92806

510K SUMMARY

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 Carotid Endarterectomy Shunt Catheter for commercial distribution. The common names for the device are silicone carotid shunt catheter, carotid catheter and carotid shunt.

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 LMI Carotid Endarterectomy Shunt Catheter consists of a multi-lumen, straight or tapered silicone tube with or without stainless steel wire reinforcement with one or more silicone balloons formed at either or both ends. Additional silicone tubes are attached at the approximate center and at approximately 90 degrees of the main tube for communicaton with the main central lumen as well as the smaller lumen used to inflate the balloons that are located on either or both ends. The proximal ends of the balloon inflation tubes are fitted with a female luer connector and may on some models incorporate a strain relief that is bonded to the silicone shaft. The proximal end of the central communicating tube is also fitted with a female luer connector and may on some models incorporate a strain relief that is bonded to the silicone shaft. Stopcocks are attached to the female luer connectors on all connecting tubes. The ends of the main multi-lumen tube are end formed to create a soft leading edge. The main multi-lumen tube may also be tapered in certain models to enchance blood flow.

CLASSIFICATION: The "DEVICE" is a Class II Medical device and has a classification number of 74GBK 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 use during a carotid endarterectomy procedure to provide temporary carotid artery bypass (blood flow) for cerebral circulation. The device is designed as a temporary indwelling catheter and is not intended for permanent placement.

PRINCIPLE OF OPERATION: Carotid Endarterectomy Shunt Catheters are generally used in procedures for maintaining blood flow to the cerebral area during temporary occlusion of the carotid artery. The affected blood vessel is accessed surgically and the appropriately sized carotid shunt for the blood vessel is selected. The shunt is inserted first into the common carotid artery. The large balloon is inflated with saline until the blood flow has been obstructed. The central silicone tubing is clamped to permit back-flow into the irrigation tube through the stopcock and into the syringe. The smaller balloon is the then inserted into the internal carotid artery and flow is established. The balloon is then inflated with saline with sufficient volume to occlude arterial flow around the shunt and to prevent balloon slippage.

SUBSTANTIAL EQUIVALENCE: The "DEVICE" is substantially equivalent to the VASCUSHUNT CAROTID SILICONE CATHETER made by Research Medical, Inc., the PRUIT-INAHARA CAROTID SHUNT made by Ideas for Medicine, and the SUNDT INTERNAL AND EXTERNAL CAROTID SHUNTS made by Heyer-Schulte NeuroCare. The materials of construction, methods of construction and the packaging and sterilization of the "DEVICE" are identical to the approved LMI Embolectomy catheter 510(k) 954760. The Indicated Use of the Device is substantially equivalent to the Vascushunt Carotid Silicone Catheter, the Pruit-Inahara Carotid Shunt, and the Sundt Internal and External Carotid Shunt Catheters.

Please Address all correspondence and questions to:

Mr. Daniel R. Lucas, President
Lucas Medical, Inc.
1751 S. Douglass Road

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 30 1999

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

Re: K983802
Carotid Endarterectomy Shunt Catheter
Regulatory Class: II (two)
Product Code: MJN
Dated: May 14, 1999
Received: June 10, 1999

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 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). 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 (Premarket 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.

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/dsma/dsmamain.html".

Sincerely yours,

Thomas J. Callahan

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

Enclosure

510(k) Number (if known): K983802

Device Name: LMI Carotid Endarterectomy Shunt Catheter

Indications For Use:

INDICATIONS FOR USE

The LMI Carotid Endarterectomy Shunt Catheter is intended for use during a carotid endarterectomy procedure to provide temporary carotid artery bypass (blood flow) for cerebral circulation.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Christopher M. Hoss for Callahan

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices

510(k) Number _____

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ___

(Optional Format 1-2-96)