K043033

DEC - 3 2004

510(k) SUMMARY

The 510(k) Summary is submitted in accordance with 21 CFR Part 807.92.

Submitter's Name:	LeMaitre Vascular, Inc.
Submitter's Address:	63 Second Avenue Burlington, MA 01803
Telephone: **Fax**:	781/221-2266 781/221-2223
Contact Person: **Date Prepared**:	Saba Modjarrad 10/29/04
Device Trade Name:	Pruitt-Inahara Outlying Carotid Shunt
Device Common Name:	Carotid Shunt
Device Classification Name:	Catheter, Intravascular Occluding, Temporary
Device Classification:	Class II

Summary of Substantial Equivalence:

The design, materials, method of delivery and intended use features of Next Generation Pruitt-Inahara Outlying Carotid with 10.5F diameter is substantially equivalent with regard to these features in the predicate device, the Pruitt-Inahara Outlying Carotid Shunt (K960715, September 9, 1996).

Device Description:

The Next Generation Pruitt Carotid Shunt is designed to serve as a temporary blood conduit connecting one section of a vessel to a second area of the same vessel. This allows blood to continuously flow to the patient's brain during an endarterectomy procedure. The device is manufactured using a clear, plastic, sterile conduit, which is held in place by a stabilization technique on both ends of the conduit.

The Next Generation Pruitt Carotid Shunt is a multi-lumen device with balloons on both the distal (internal carotid) and proximal (common carotid) ends of the shunt. The balloons, when inflated independently, act as a stabilization mechanism to maintain the position of the shunt when it is placed within the common and internal carotid arteries. An external safety balloon, located on the inflation arm that is inserted into the internal carotid artery, acts as a mechanism

to relieve pressure on the internal carotid balloon in the event it is inflated above a predetermined pressure. The external safety balloon feature reduces the possibility of balloon over-inflation and resultant vessel damage.

Intended Use:

The Pruitt-Inahara Outlying Carotid Shunt is indicated for use in carotid endarterectomy as a temporary conduit to allow for blood flow between the common and internal carotid arteries.

Technological Characteristics:

Comparisons of the new and predicate devices show that technological characteristics such as materials, biocompatibility, performance properties, sterilization and packaging of the proposed device are substantially equivalent to the currently marketed predicate devices. The design modifications of the new carotid shunt compared to that of the predicate carotid shunts are:

- Blue tint added to the Common Carotid Inflation Arm
- Black locating stripes on the stopcock and shunt body were removed
- Yellow tint added to the safety sleeve
- For the Pellethane shunt body:
  - Decrease in durometer
  - Increase in French size
  - Change from circular to triangular cross section of shunt body tubing

- For the Tecoflex shunt body:
  - Additional Material
  - Decrease in durometer
  - Increase in French size
  - Change from circular to triangular cross section of shunt body tubing

Performance Data:

The safety and effectiveness of the Next Generation Pruitt-Inahara Outlying Carotid Shunt has been demonstrated through data collected from bench tests and analyses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 3 2004

LeMaitre Vascular, Inc.
c/o Ms. Sara Modjarrad
Regulatory Affairs Specialist
63 Second Avenue
Burlington, MA 01803

Re: K043023
Pruitt-Inahara Outlying Carotid Shunt and the Inahara-Pruitt Inlying Carotid Shunt
Regulation Number: 21 CFR 870.4450
Regulation Name: Catheter, Intravascular Occluding, Temporary
Regulatory Class: II (two)
Product Code: MJN
Dated: October 29, 2004
Received: November 3, 2004

Dear Ms. Modjarrad:

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) 276-0120. 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,

Donna R. Lechner

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K043023

Device Name: Next Generation Pruitt-Inahara Outlying Carotid Shunt

Indications For Use:

1. The carotid shunts are indicated for use in carotid endarterectomy as a temporary conduit to allow for blood flow between the common and internal carotid arteries.

2. The size 8 French Shunt is intended for use on those patients whose vasculature is too small to accommodate a size 9 French Shunt.

Prescription Use X 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)

Donna R. Lechner

(Division Sign-Off)
Division of Cardiovascular Devices

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