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MAY 27 2005

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:**	Amy Watzke 04/04/05
Device Trade Names:	Pruitt® F3 Outlying Carotid Shunt (without T-Port) Pruitt® F3 Outlying Carotid Shunt (with T-Port) Pruitt® F3 Inlying Carotid Shunt (with T-Port) Pruitt® F3 Inlying Carotid Shunt (without T-Port)
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 the Pruitt® F3 Outlying Carotid Shunt without T-port, the Pruitt® F3 Outlying Carotid Shunt with T-port, the Pruitt® F3 Inlying Carotid Shunt with T-port and the Pruitt® F3 Inlying Carotid Shunt without T-port (the Pruitt® F3 Shunts) are substantially equivalent with regard to these features in the predicate device, the Next Generation Pruitt-Inahara® Outlying Carotid Shunt (K043023, December 3, 2004).

Device Description:

The proposed Pruitt® F3 Shunts are designed to serve as temporary blood conduits 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 Pruitt® F3 Shunts are tri-lumen devices 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 leading to the distal (internal carotid) balloon, acts as a mechanism to relieve pressure on the internal carotid balloon in the event it inflates above the maximum stated volume. The external safety balloon feature reduces the possibility of balloon over-inflation and resultant vessel damage.

Intended Use:

The Pruitt® F3 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.

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 devices are substantially equivalent to the predicate device. The design modifications of the new Pruitt® F3 Shunts compared to that of the predicate carotid shunt are:

- Physical Changes
  - Removal of the T-Port (for Outlying without T-Port and Inlying without T-Port versions)
  - Reduction in the length of the shunt body (for Inlying versions)
  - Reduction in French size from 10.5F to 10F

Performance Data:

The safety and effectiveness of the proposed Pruitt® F3 Shunts 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

MAY 27 2005

LeMaitre Vascular, Inc.
c/o Ms. Amy Watzke
International Regulatory Affairs Specialist
63 Second Avenue
Burlington, MA 01803

Re: K051067
Pruitt® F3 Outlying and Inlying Carotid Shunts with and without T-Port
Regulation Number: 21 CFR 870.4450
Regulation Name: Catheter, Intravascular Occluding, Temporary
Regulatory Class: Class II (Two)
Product Code: MJN
Dated: April 4, 2005
Received: April 26, 2005

Dear Ms. Watzke:

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/industry/support/index.html.

Sincerely yours,

Donna R. Mechanic

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): K051067

Device Name: Pruitt® F3 Outlying Carotid Shunt (without T-Port)
Pruitt® F3 Outlying Carotid Shunt (with T-Port)
Pruitt® F3 Inlying Carotid Shunt (without T-Port)
Pruitt® F3 Inlying Carotid Shunt (with T-Port)

Indications For Use:

1. The Pruitt-Inahara®, Inahara-Pruitt® and Pruitt® F3 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 Vachuska

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K051067