K071367
p. 1 of 1

LeMaitre® VASCULAR

ɔre Than The Valvulotome.

AUG 2 9 2007

510(k) SUMMARY SAFETY and EFFECTIVENESS INFORMATION

as required by Safe Medical Devices Act of 1990 and codified in 21 CFR Part 807.92 upon which substantial equivalence is based.

Flexcel® Carotid Shunt (inlying)

Date Prepared: 05/15/2007

Submitter's Name: LeMaitre Vascular, Inc.
Address: 63 Second Avenue
Burlington, MA 01803

Company Contact: Minnie Mildwoff, RAC
Sr. Regulatory Affairs Specialist
Tel: (781) 221-2266
Fax:(781) 425-5049

Device Name
Trade Name: Flexcel® Carotid Shunt (inlying)
Device Common Name: Carotid Shunt
Device Classification Name: Catheter, Intravascular Occluding, Temporary

Summary of Substantial Equivalence:

The design, materials, method of delivery and intended use features of Flexcel™ Carotid Shunt (inlying) is substantially equivalent with regard to these features in the predicate device, the Pruitt F3 Carotid Shunt (K051067) and LeMaitre Vascular Straight Carotid Shunt (K033159)

Device Description:

The Flexcel™ 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 Flexcel Carotid Shunt is a straight design shunt packaged in 5-unit packages providing a variety of sizes from 8-14 French.

Intended Use:

The Flexcel™ 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.

Performance Data:

The safety and effectiveness of the Flexcel™ 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

AUG 29 2007

LeMaitre Vascular, Inc.
c/o Ms. Minnie Mildwoff
Senior Regulatory Affairs Specialist
63 Second Avenue
Burlington, MA 01803

Re: K071367
Flexcel Carotid Shunt (Inlying)
Regulation Number: 21 C.F.R. § 870.4450
Regulation Name: Vascular clamp
Regulatory Class: Class II
Product Code: MJN
Dated: August 16, 2007
Received: August 22, 2007

Dear Ms. Mildwoff:

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); labcling (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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Vechmes

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

Enclosure

LeMaitre VASCULAR

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Indications for Use

510(k) Number (if known): K071367

Device Name: Flexcel Carotid Shunt (inlying)

Indications For Use:

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.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (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. Vochner

(Division Sign-Off)

Division of Cardiovascular Devices

510(k) Number K071367

Page 1 of 1

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