K111884
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Section 5.0 **510(k) SUMMARY OF SAFETY AND EFFECTIVENESS** JUL 29 2011

A. Submitter Information

Submitter's Name:	LeMaitre Vascular Inc.
Address:	63 Second Avenue Burlington, MA 01803
Telephone:	781-221-2266
Fax:	781-425-5049
Contact Person:	Andrew Hodgkinson, Vice President Clinical, Regulatory and Quality Affairs
Date of Preparation:	July 28, 2011

B. Subject Device

Trade Name:	OTW-Expandable LeMaitre Valvulotome
Common/Usual Name:	Valvulotome
Classification Name:	Valvulotome (870.4885, Product Code MGZ)

C. Predicate Device Name:

Trade Name:	Expandable LeMaitre Valvulotome, (K980723)

D. Device Description:

The OTW ELV is a self-centering and self-sizing catheter used for cutting valves in the saphenous vein while navigating over a guidewire.

E. Intended Use:

The Over-The-Wire Expandable LeMaitre Valvulotome is indicated for cutting saphenous vein valves during in-situ bypass.

F. Summary of Technological Characteristics

The OTW ELV navigates the vein via passage over a guidewire. Upon deployment, the centering hoops expand to the walls of the vessel. As the device is retracted, the hoops keep the blades away from the vessel while allowing them to cut the valves as they are encountered.

G. Performance Data:

Biocompatibility testing was conducted in accordance with AAMI/ANSI/ ISO 10993-1: 2003 Biological Evaluation of Medical Devices- Part 1 Evaluation and Testing. The following biocompatibility tests were conducted with results that demonstrated that the proposed device is non-toxic and non-sensitizing to biological tissues consistent with its intended use:

- ISO MEM Elution Assay
- Complement Activation C3a and SC5b-9 Assay
- Platelet & Leukocyte Count

- ASTM Hemolysis Assay
- Partial Thromboplastin Time
- ISO Intracutaneous Reactivity
- Murine Local Lymph Node Assay
- ISO Acute Systemic Injection Test in the Mouse

The proposed OTW-ELV was tested through in-vitro bench-top testing as well as in-vitro cadaver testing. The following performance bench testing was completed for the OTW-ELV:

- Tensile testing of all bond joints
- Dimensional verification against product design specifications
- Guidewire compatibility
- Trackability through in-vitro models (simulated use)
- Trackability through cadaver models (simulated use)
- Efficacy – cutting of in-vitro vein valves (simulated use)
- Efficacy – cutting of cadaver vein valves (simulated use)
- Hemostasis
- Fatigue testing

All test results demonstrated that the materials chosen, the manufacturing process, and the design utilized for OTW-Expandable LeMaitre Valvulotome met the established specifications necessary for consistent performance during its intended use as well as substantial equivalence to its predicate.

H. Conclusion:

LeMaitre Vascular has demonstrated that the OTW-Expandable LeMaitre Valvulotome is substantially equivalent to the predicate device based on its indications for use and fundamental scientific technology.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUL 29 2011

LeMaitre Vasculature
c/o Andrew Hodgkinson
Vice President, Clinical, Regulatory, & Quality Affairs
63 Second Avenue
Burlington, MA 01803

Re: K111884
Trade/Device Name: OTW-Expandable LeMaitre Valvulotome
Regulation Number: 21 CFR 870.4885
Regulation Name: External Vein Stripper
Regulatory Class: Class II
Product Code: MGZ
Dated: June 30, 2011
Received: July 1, 2011

Dear Mr. Hodgkinson:

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. Please note: CDRH does not evaluate information related to contract liability warranties. However, we remind you that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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

Enclosure

SECTION 4: INDICATION FOR USE STATEMENT

510(k) Number (if known): K111884

Device Name: Over-The-Wire Expandable LeMaitre Valvulotome

Indications for Use:

The Over-The-Wire Expandable LeMaitre Valvulotome is indicated for cutting saphenous vein valves during In Situ bypass.

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 ID NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K111884