K132190

510(k) Summary

Submitter Information:

Name:	LeMaitre Vascular, Inc.
Address:	63 Second Avenue Burlington, MA 01803
Contact Person:	Anna Kasseris Regulatory Affairs Specialist Phone: 781-425-1706 Fax: 781-425-5049 Email: akasseris@lemaitre.com
Date Prepared:	July 10, 2013
Trade Name:	Expandable LeMaitre Valvulotome (ELV), Over-the-wire LeMaitre Valvulotome
Common Name:	Valvulotome
Classification Name:	External Vein Stripper
Class:	II (two)
Classification Panel:	Cardiovascular
Product Code:	MGZ
Establishment:	63 Second Avenue Burlington, MA 01803

AUG 05 2013

Device Description:	The ELV and OTW-LV are self-centering and self-sizing valvulotome used for blind lysis of vein valves. Once the valves have been rendered ineffectual, it can then be utilized as an arterial conduit. Centering hoops keep the devices centered in the vein and prevent the valve-cutting blades from damaging the vein wall. The size of hoops and blades adjusts to the internal diameter of the vein as the valvulotome is being drawn through the vessel. The OTW-LV facilitates navigation of the vein with the assistance of a guidewire.
Proposed Intended Use:	It is used for the treatment of vascular disorders and more particularly for excising or disrupting venous valves.
Predicate Devices:	K080178- Valvulotome by Koven,
Summary of Technological Characteristics:	The ELV and OTW-LV are self-centering and self-sizing valvulotome used for blind lysis of vein valves. Upon deployment the centering hoops expand to the walls of the vessel. As the device is retracted the hoops keep the blade away from the vessel while allowing them to lyse the valves. The OTW LV navigates the vein via a passage over a guidewire.
Summary of Product Testing:	No additional testing was performed for this submission.
Biocompatibility:	The biocompatibility of the devices were tested in accordance to ISO 10993 guidelines.
Sterilization:	The device is validated for ethylene oxide (EtO) gas sterilization according to ANSI/AAMI/ISO 11135-1:2007, "Sterilization of Medical Devices – Validation and Routine Control of Ethylene Oxide Sterilization".
Functional/Safety Testing:	No additional testing was performed for this submission.
Summary of Pre-clinical Study:	No preclinical study was performed for this submission.

Conclusion: LeMaitre Vascular has demonstrated that the ELV and OTW LeMaitre Valvulotome, are substantially equivalent to the predicate device based on its intended use and fundamental scientific technology.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

August 5, 2013

LeMaitre Vascular, Inc.
c/o Anna Kasseris
Regulatory Affairs Specialist
63 Second Avenue
Burlington, MA 01803

Re: K132190
Trade/Device Name: Expandable Le Maitre Valvulotome and Over-the-wire LeMaitre Valvulotome
Regulation Number: 21 CFR 870.4885
Regulation Name: Valvulotome, External Vein Stripper
Regulatory Class: Class II
Product Code: MGZ
Dated: July 10, 2013
Received: July 15, 2013

Dear Ms. Kasseris:

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. We remind you, however, 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 contact 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. 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,

Bram D. Zuckerman -S

Bram D. Zuckerman, Ph.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): K132190

Device Name: Expandable LeMaitre Valvulotome, Over-the-Wire LeMaitre Valvulotome

---

Indications for Use: It is used for the treatment of vascular disorders and more particularly for excising or disrupting venous valves.

Prescription Use _X_ and/or Over-The Counter Use_____

(Part 21 CFR 801Subpart 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)

Bram D. Zuckerman -S
2013.08.05 16:28:03 -04'00'