DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

October 17, 2014

Lemaitre Vascular, Inc.
% Anna Kasseris
Regulatory Affairs Specialist
63 Second Avenue
Burlington, Massachusetts 01803

Re: K142660
Trade/Device Name: Antegrade LeMills Valvulotome
Regulation Number: 21 CFR 870.4885
Regulation Name: External Vein Stripper
Regulatory Class: Class II
Product Code: MGZ
Dated: September 15, 2014
Received: September 18, 2014

Dear Anna 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 Industry and Consumer Education 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" (21 CFR 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 Industry and Consumer Education 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,

Kenneth J. Cavanaugh -S

for

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142660

Device Name
Antegrade LeMills Valvulotome

Indications for Use *(Describe)*
The LeMills Valvulotomes are intended to cut venous valves.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510k Summary

Submitter's Information

Name:	LeMaitre Vascular, Inc.
Address:	63 Second Avenue Burlington, MA 01803
Phone:	781-425-1706
Fax:	781-425-5049
Contact Person:	Anna Kasseris Regulatory Affairs Specialist Email: akasseris@lemaitre.com
Date Prepared:	September 15, 2014
Device Name:	Antegrade LeMills Valvulotome
Trade Name:	LeMills Valvulotome
Common Name:	External Vein Stripper
Classification Name:	Cardiovascular
Classification Panel:	21CFR §870.4885
Class:	II (2)
Product Code:	MGZ
Establishment Registration:	1220948
Establishment:	63 Second Avenue Burlington, MA 01803
Predicate Device:	LeMills Valvulotome (Retrograde) K132047
Reference Device:	Mills Valvulotome (Antegrade), Pre-amendment
Device Description:	The Antegrade LeMills Valvulotome consists of small metal antegrade cutting blade with atraumatic distal edge. The blade is a part of a long stainless steel wire that allows it to be inserted into the venous anatomy. It is held by a plastic handle. It is designed for cutting the venous valves. Once the valves have been rendered ineffectual, the vein can then be utilized as an arterial conduit.
Intended Use:	The LeMills Valvulotome is intended to cut venous valves.

Summary of Technological Characteristics:	The Antegrade LeMills Valvulotome maintains the same technological characteristics as the predicate Retrograde LeMills Valvulotome.
Functional/Safety Testing:	The verification activities conducted indicate that Antegrade LeMills Valvulotome device meets the product performance requirements of the device specifications and does not raise any additional safety issues.
Sterilization:	The device is ethylene oxide (EO) sterilized according to ANSI/AAMI/ISO 11135-1:2007, "Sterilization of Medical Devices – Validation and Routine Control of Ethylene Oxide Sterilization"
Biocompatibility:	Biocompatibility of the device has been assessed according to ISO 10993 guidelines for an externally communicating device with limited contact duration (<24 hours), in circulating blood. The assessment concluded that Antegrade LeMills is biocompatible.
Summary of Product Testing:	The following tests have been completed to evaluate the safety and performance of the Antegrade LeMills Valvulotome: • Dimensional Comparison • Sharpness Test (Effectiveness Test) • Visual Inspection • Joint Tensile Strength (Pull Test)
Summary of Pre-clinical Study:	N/A
Conclusion:	LeMaitre Vascular has demonstrated that the Antegrade LeMills Valvulotome substantially equivalent to the predicate devices based on its intended use and fundamental scientific technology.