K132047

510 (k) Summary

Submitter's information:

NOV 05 2013

Name:	LeMaitre Vascular, Inc.
Address:	63 Second Avenue Burlington, MA USA 01803
Phone:	781-425-1727
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Contact Person:	Bryan Cowell, MSc., RAC
Date of preparation:	July 1, 2013
Device Name:	LeMills Valvulotome
Trade Name.	LeMills Valvulotome
Common/ Classification Name:	External Vein Striper
Classification Panel:	21CFR §870.4885
Class:	II (2)
Product Code:	MGZ

Establishment Registration: 1220948

Establishment: LeMaitre Vascular, Inc., 63 Second Avenue, Burlington, MA USA 01803

Owner/Operator: 1220948

Proposed Device Description:

The LeMills Valvulotome consists of small metal retrograde cutting blade with atraumatic distal edge. The blade is a part of a long section of 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.

Proposed Intended Use:

The LeMills Valvulotome is intended to cut venous valves.

Predicate Device:

Device Name: Mills Valvulotome, Pre-amendment device.

Substantial Equivalence:

Fundamental Scientific Technological Characteristics:

The LeMills Valvulotome maintains the same fundamental Scientific Technology as the Mills Valvulotome and is used to cut venous valves.

Functional/ Safety testing:

The verification activities conducted indicate that LeMills Valvulotome device meets the product performance requirements of the device specifications and does not raise any additional safety issues.

Sterilization:

The device is validated for ethylene oxide (EO) sterilization according to ANSI/AAMI/ISO 11135-1:2007, "Sterilization of Medical Devices – Validation and Routine Control of Ethylene Oxide Sterilization"

Biocompatibility:

Materials used in this device were subjected to Biocompatibility assessment according to ISO 10993 guidelines for an externally communicating device with limited contact duration (<24 hours), in circulating blood. The assessment concluded that LeMills is biocompatible.

Summary of Product Testing:

The following tests have been completed to evaluate the safety and performance of LeMills Valvulotome compared with the predicate device:

- *Dimensional comparison*
- *Sharpness Test (Effectiveness Test)*

Conclusion:
LeMaitre Vascular has demonstrated that the LeMills Valvulotome is 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

November 5, 2013

LeMaitre Vascular, Inc.
Andrew Hodgkinson
Vice President of Regulatory, Quality, and Clinical
63 Second Avenue
Burlington, MA 01803

Re: K132047
Trade/Device Name: LeMills Valvulotome
Regulation Number: 21 CFR 870.4885
Regulation Name: External Vein Stripper
Regulatory Class: Class II
Product Code: MGZ
Dated: October 24, 2013
Received: October 28, 2013

Dear Andrew 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. 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" (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 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, 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) K132047/S001

Device Name LeMills Valvulotome

Indications for Use The LeMills Valvulotome is intended to cut venous valves.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use____X_____ OR Over-The-Counter Use_____
(Per 21 CFR 801. 109)

Bram D. Zuckerman -S
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