October 30, 2019

LeMaitre Vascular, Inc.
Xiang Zhang
VP of Regulatory
63 Second Avenue
Burlington, Massachusetts 01803

Re: K190267
Trade/Device Name: EZE SIT Valvulotome
Regulation Number: 21 CFR 870.4885
Regulation Name: External Vein Stripper
Regulatory Class: Class II
Product Code: MGZ
Dated: September 26, 2019
Received: September 30, 2019

Dear Xiang Zhang:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Carmen Gacchina Johnson, Ph.D.
Acting Assistant Director
DHT2B: Division of Circulatory Support,
Structural and Vascular Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190267

Device Name
EZE SIT Valvulotome

Indications for Use *(Describe)*
The EZE SIT Valvulotome is intended to render venous valves incompetent during in situ bypass procedures. This includes distal infrainguinal bypass when a non-anatomic position is required (e.g., profunda to anterior tibial artery), composite vein infrainguinal bypass, or aorto-renal bypass procedures.

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.

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SECTION 8: 510(k) Summary K190267

I. SUBMITTTER	LeMaitre Vascular, Inc. 63 Second Avenue Burlington, MA 01803
Establishment Registration	1220948
Phone:	781-425-1685
Fax:	781-425-5049
Contact Person:	Xiang Zhang VP of Regulatory Email: xzhang@lemaitre.com
Date Prepared	September 26, 2019
I. DEVICE	
Device Name:	EZE-SIT Valvulotome
Trade Name:	EZE-SIT Valvulotome
Common Name:	External Vein Stripper
Classification Panel:	Cardiovascular
Regulation Number:	21CFR §870.4885
Class:	II (2)
Product Code:	MGZ
Prior Submissions:	No prior submissions have been made for the changes detailed in this traditional 510(k).
II. PREDICATE DEVICE	Tru-Incise Valvulotome (K930011) This predicate device has not been subject to a design-related recall. No reference devices were used in this submission.

III. DEVICE DESCRIPTION:

The EZE SIT Valvulotome is a medical device utilized for disruption of venous valves, and is used in patients that suffer from peripheral vascular disease, for which an attending physician determines the relative benefit of *in situ* bypass to restore blood flow to the extremities. The EZE-SIT Valvulotome is comprised of a catheter with a luer-lock hub at the proximal end and a threaded connector at the distal end. The catheter is designed with a lumen that extends throughout its entire length. The threaded connector allows attachment of 2 mm, 3 mm and 4 mm diameter cutting heads. These cutting heads are also configured with a central lumen. This design allows the physician to select the cutter head diameter that is best suited for the particular vessel being prepared. The central lumen allows irrigation during the procedure. The cutting head design minimizes vessel wall contact while effectively disrupting valve leaflet tissue. The EZE SIT Valvulotome is surgically invasive and intended for less than 24-hour use. This medical device has no software components. This device is not an *in vitro* diagnostic device.

IV. INDICATIONS FOR USE:

The EZE SIT Valvulotome is intended to render venous valves incompetent during in situ bypass procedures. This includes distal infrainguinal bypass when a non-anatomic position is required (e.g., profunda to anterior tibial artery), composite vein infrainguinal bypass, or aorto-renal bypass procedures.

V. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Overall Description, Device Design: The EZE SIT Valvulotome comprises a catheter with a luer lock hub at the proximal end, a threaded connector at the distal end, and a lumen that extends throughout its entire length. The threaded connector allows attachment of 2mm, 3mm and 4mm diameter cutting heads, which also feature a central lumen. The design allows the physician to select the cutter head diameter best suited for a particular vein being prepared. The central lumen allows irrigation during the procedure. The cutting heads minimize vessel wall contact while effectively disrupting valve leaflet tissue. The design of the EZE SIT Valvulotome has not changed since the original clearance (K930011).

Materials: The materials of the EZE SIT Valvulotome are identical to those used for the Tru-Incise Valvulotome (K930011). All components are patient-

contacting unless indicated otherwise. EZE SIT is surgically invasive and intended for <24h use.

Part Name	Material
EZE SIT Threaded Leader, 2mm	303 Stainless Steel
EZE SIT Threaded Leader, 3mm	
EZE SIT Threaded Leader, 4mm	
EZE SIT Connecting Cannula, 2mm	304 Stainless Steel
EZE SIT Connecting Cannula, 3mm	
EZE SIT Connecting Cannula, 4mm	
EZE SIT Cutter Head with Edge, 2mm	303 Stainless Steel
EZE SIT Cutter Head with Edge, 3mm	
EZE SIT Cutter Head with Edge, 4mm	
EZE SIT Introduction Head	303 Stainless Steel
EZE SIT Vein Sleeve	Polyurethane 75D/ Barium Sulfate
EZE SIT Head Holder T (non patient-contacting)	Nylon
EZE SIT Small Head Holder Tubing (non-patient contacting)	Silicone
EZE SIT Large Head Holder Tubing (non-patient contacting)	
EZE SIT Extra Large Head Holder Tubing (non-patient contacting)	
EZE SIT Vein Sleeve Tether Tubing (non-patient contacting)	
EZE SIT Tributary Sleeve, 2mm	Polyurethane/ Barium Sulfate
EZE SIT Tributary Sleeve, 4mm	
EZE SIT Shaft Spring	304 Stainless Steel
EZE SIT Threaded	303 Stainless Steel

Connector	
EZE SIT Catheter Hub	Acrylonitrile Butadiene Styrene (ABS)
Packaging Materials (all non-patient contacting)	
EZE SIT Head Holder Pouch	Tyvek/Polyethylene Terephthalate (PET)/ Polyethylene (PE)
EZE SIT Device Pouch	
EZE SIT Tyvek Lid	Tyvek
EZE SIT Packaging Tray	Polyethylene Terephthalate Glycol (PETG)

Chemical Composition: All of the components of the EZE SIT Valvulotome remain unchanged from the original device design cleared in K930011.

Energy Source: The EZE SIT Valvulotome is a device that transduces manual force provided by the user into the lysis of valve cusps, thus allowing retrograde blood flow in a vein. EZE SIT uses and provides no other source of energy of electromechanical, radiological or other origin. The aspect of energy source supplied to the medical device remains unchanged from the predicate device cleared in K930011.

Summary: All aspects of the medical device, including the design, materials, chemical composition and energy source of the subject device remain unchanged from the original predicate device cleared in K930011, and thus support substantial equivalence of the subject to the predicate device.

VI. PERFORMANCE DATA

N/A. This submission is intended to simply indicate a new manufacturer for a currently cleared device design that has not changed since its clearance (K930011). This submission includes 3 types of nonclinical data, including Sterilization, Shelf Life/Aging, and Biocompatibility.

Sterilization: The EZE SIT is Ethylene Oxide (EtO) sterilized to a Sterility Assurance Level (SAL) of 10^{-6}. Sterilization is validated with half-cycle using ISO 11135-1: 2014. Residuals measured at 48h after sterilization indicate that the device has a maximum of EtO of 0.6 mg, and a maximum of <0.1 mg of Ethylene Chlorohydrin (ECH) (VP-160032). Endotoxin is measured by LAL method.

Shelf Life/Aging studies provided here confirmed the shelf life of 2.5 years as reported for the predicate

	device (K930011), but also extended the shelf life to 6 years, all based on accelerated aging. Thus, the Shelf Life/Aging studies support the conclusion of substantial equivalence. **Biocompatibility**: Upon acquisition of the right to manufacture the device for sale outside the US market, LeMaitre Vascular performed a biocompatibility battery that recapitulated the same tests as performed for the predicate device cleared in K930011. Like the predicate device, the subject device detailed here passed all tests in the biocompatibility battery, thus supporting substantial equivalence of these devices.
Summary of non-clinical and clinical Studies:	None.
VII. CONCLUSION:	LeMaitre Vascular has demonstrated that the EZE SIT Valvulotome is substantially equivalent to the predicate device based on its intended use and fundamental scientific technology, and that the subject device is as safe, as effective, and performs as well as the predicate device.