March 31, 2022

LeMaitre Vascular Inc.
Anurag Gadgil
Sr. Regulatory Affairs Specialist
63 Second Ave
Burlington, Massachusetts 01803

Re: K212894
Trade/Device Name: PhasTIPP
Regulation Number: 21 CFR 870.4885
Regulation Name: External Vein Stripper
Regulatory Class: Class II
Product Code: DWQ
Dated: February 9, 2022
Received: February 14, 2022

Dear Anurag Gadgil:

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,

for Carmen Johnson, PhD
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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212894

Device Name
PhasTIPP System

Indications for Use *(Describe)*
The PhasTIPP System is indicated for use in ambulatory phlebectomy procedures for the resection and ablation of varicose veins. The Illuminator is also indicated for use without the Resector for visualization of varicose veins and infusion of tumescent solution during an ambulatory phlebectomy procedure.

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 5
510(K) SUMMARY

Submitter's information

Name:	LeMaitre Vascular, Inc.
Address:	63 Second Avenue Burlington, MA,01803. USA
Phone:	781-362-5412
Contact Person:	Anurag Gadgil
Date of preparation:	March 30, 2022
Device Name:	PhasTIPP System
Trade Name:	PhasTIPP
Common/ Classification Name:	External Vein Stripper
Classification Panel:	21CFR §870.4885
Class:	II (2)
Product Code:	DWQ
Cardiovascular:	Cardiovascular

Subject Device Description:

The PhasTIPP System consists of an Illuminator and a Resector. During the surgical procedure, the illuminator shaft is placed through an incision under the skin with its light-emitting end to provide intense light for a better visualization of the varicose veins. A port that runs along the illuminator shaft is used to infuse tumescence solution to cause the contraction of varicosities, which aids vein visualization by creating a subcutaneous fluid pocket through which the illuminator's light can disperse. A powered resector, positioned through a different incision can then be used to morcellate and aspirate the varicosities.

The PhasTIPP Illuminator consists of two devices: a reusable Illuminator Handpiece and a disposable Illuminator.

The Handpiece provides illumination controls and contains an LED to provide intense light. The Handpiece is powered with new batteries for each new surgical procedure (Duracell CR 123a

cell). The handpiece is provided non-sterile and must be covered with the microbial barrier sheath attached to the Disposable Illuminator in the sterile field before the procedure begins.

The Disposable Illuminator includes, in addition to the microbial barrier sheath, a distal stainless steel fiber optic light shaft. When connected to a peristaltic pump, the Disposable Illuminator can also infuse tumescence.

The PhasTIPP Resector consists of two devices: a reusable Resector Handpiece and a Resector Disposable (available in two diameters, 4.5mm and 5.5mm). The Disposable Resector also connects to a peristaltic suction pump to remove the resected varicosities.

The Resector Handpiece provides controls for the operation of the rotation blades on the Disposable Resector and is powered with a set of new batteries (TLM-1550 HPM cell), for each surgical procedure. The Resector Handpiece is provided non-sterile and must be covered with the microbial barrier sheath attached to the Disposable Resector in the sterile field.

The Control Unit that was a large equipment in the predicate device is displaced in the subject device. Instead, the Resector Handpiece and the Illuminator Handpiece control the disposable resector and illuminator in the subject device.

Intended Use:

The PhasTIPP System is indicated for use in ambulatory phlebectomy procedures for the resection and ablation of varicose veins. The Illuminator is also indicated for use without the Resector for visualization of varicose veins and infusion of tumescent solution during an ambulatory phlebectomy procedure.

Predicate Device:

510(k):	K032387
Device Name:	Trivex System
SE Date:	10/29/2003
Regulation Number:	21CFR §870.4885
Device Class Name:	External Vein Stripper
Device Class:	II
Product Code:	DWQ

Summary of Technological Characteristics Comparison with Predicate:

Characteristic	Predicate Device: Trivex	Subject Device: PhasTIPP
Design – Patient Interacting Components	The distal ends of the devices that interact with the patient include the Illuminator distal shaft (produces light and infuses) and the Resector distal shaft (rotates, cuts, and provides suction).	The distal ends of the devices that interact with the patient include the Illuminator distal shaft (produces light and infuses) and the Resector distal shaft (rotates, cuts, and provides suction).
Design – User Interacting Components	The proximal ends of the devices that the user interacts with include the control box with buttons/settings, the Resector MDU with an additional button, and the Illuminator (no controls).	The proximal ends of the devices that the user interacts with include the Resector Handpiece with two buttons and the Illuminator with one button.
Materials	Primarily stainless steel shafts, PEEK MDU handle, silicone and PVC tubing, and ABS.	Primarily stainless steel shafts, PEEK MDU handle, silicone and PVC tubing, and ABS.
Energy Source	110V wall outlet	Resector: 4.1V Tadiran battery Illuminator: CR123 battery
Sterilization	Disposables: ETO Reusables: Steam (on-site)	Disposables: ETO Reusables: None (ETO sterilized microbial barrier covers handpieces)

Summary of Product Testing:

The following tests have been completed to evaluate the performance of the subject device compared with the predicate device:

- Illuminator Design Validation
  Shaft ø (in)
  Length: Shaft (in)
  Length: IV Spike to Pump (in)
  Length: Pump Tube (in)
  Length: Pump to Hub (in)
  Flow Rate (ml/min)
  Light Output (lumens)
  Leak Testing
  Sheath Length (in)
  Usability Through Sheath
  Sheath Maintains Microbial Barrier
  Tensile Strength: Hub to Shaft (lbf)
  Torque Strength: Disposable (in-lb)
  Tensile Strength: Disposable to HP (lbf)
  Tensile Strength: Tubing to Hub (lbf)
  Tensile Strength: IV Spike to Tubing (lbf)
  Tensile Strength: Pump tube to Connectors
  Kink Test: Infusion Tubing

- Illuminator Validation System
  Basic Function
  Low Battery Functionality
  Fault Insertion and Power Supply
  Fuse testing

- Resector System Validation
  Voltage Regulation
  Motor RPM
  Home Position and Home Position Drift
  Communications and Diagnostic Logging
  Embedded Processor Hardware
  Basic Function
  Jam Clear
  Battery Critical Function
  Embedded processor/Software load

- Resector Software Integration Validation
  Integration Test- timer functionality
  Integration Test- low battery functionality
  Integration Test- low level hardware configuration of the micro-controller hardware
  Integration Test- motor state machine running
  Integration Test- functionality of the oscillation feature and software
  Integration Test- fault states related to the "anti-stall routine
  Integration Test- high motor current fault by simulating excessive motor current
  Integration Test- the motor time save and retrieve function
  Integration Test- the Real Time Clock (RTC) against the system clock
  Integration Test- battery critical lockout feature.

- Resector Design Validation
  Shaft Diameter 4.5mm
  Shaft Diameter 5.5mm
  Shaft Length 4.5mm
  Shaft Length 5.5mm
  Aspiration Tube Length
  Aspiration Tube tensile strength to Connector
  Kink Testing & Leak Testing
  Bond Tubing to Back Lid
  Aspiration Flow Rate Comparison 4.5
  Aspiration Flow Rate Comparison 5.5
  Motor Functionality Data
  Sterile Sheath: Adequate length
  Sterile Sheath: Microbial Barrier Testing
  Sterile Sheath: Maintains Contamination Barrier
  Disposable Hub to Main Shaft: Tensile Strength 4.5mm

Disposable Hub to Main Shaft: Tensile Strength 5.5mm
Disposable Hub to Shaft assembly: Torque Strength
Driven Gear to the resector inner shaft Tensile Strength 4.5mm
Driven Gear to the resector inner shaft Tensile Strength 5.5mm
Driven Gear to the resector inner shaft Torque Strength
Bonded joint between proximal hub and the backlid
Disposable Assembly to Handpiece: Tensile Strength
Distal Hub Pinned to proximal resector

- Microbial Sheath Barrier Design Validation
  Sheath Bubble Leak Test

- PhasTIPP Illuminator Injection Line Design Validation
  Pressurized Leak Testing

- PhasTIPP Illuminator Injection Line Shelf Life Validation (2 years Accelerated aging)
  Pressurized Leak Testing
  Flow Rate Measurement
  Luer Fitting Tensile Strength test
  Overall Length

- PhasTIPP Performance Testing
  System performance testing in 3D in-vitro bench test

- PhasTIPP Illuminator Heat Evaluation
  Evaluation of heat produced by PhasTIPP Illuminator

- PhasTIPP Testing to IEC 60601 Medical Electrical Equipment
  Radiated Emissions
  Electro-Static Discharge
  Radiated Field Immunity
  Power Frequency Magnetic Field

The verification activities conducted on the subject device indicate that the subject device meets the product performance specifications and the modifications do not raise any additional safety issues.

Sterilization:

The PhasTIPP Illuminator and Resector disposable assemblies are provided sterile and sterilization method is EtO gas. The sterilization validation followed the guidelines in the Product Adoption and Process Equivalence for Ethylene Oxide Sterilization AAMI TIR28:2016. The sterilization process has been validated per EN ISO 11135-1:2014.

Biocompatibility:

LeMaitre Vascular has performed biocompatibility assessment per ISO 10993-1:2018 and FDA Guidance Use of International Standard ISO 10993-1 “Biological evaluation of medical device- Part 1.” The Phas TIPP Illuminator and the Resector are categorized as External Communicating Device, Contact Circulating Blood, for limited use (<24 h).
The biocompatibility tests demonstrated that the subject device is biocompatible.

Conclusion:

The PhasTIPP System is substantially equivalent to the predicate device.