December 21, 2022

LimFlow, Inc.
Zachary Woodson
VP of Regulatory Affairs & Quality
3031 Tisch Way - 110 Plaza West
San Jose, California 95128

Re: K221902
Trade/Device Name: LimFlow Vector
Regulation Number: 21 CFR 870.4885
Regulation Name: External Vein Stripper
Regulatory Class: Class II
Product Code: MGZ
Dated: June 28, 2022
Received: June 30, 2022

Dear Zachary Woodson:

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,

Rohini Retarekar -S

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)*
K221902

Device Name
LimFlow Vector™

Indications for Use *(Describe)*
The LimFlow Vector is intended for the treatment of vascular disorders and more particularly for excising or disrupting 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.

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5 510(k) Summary

LimFlow Vector™

510(k) Summary

21 CFR807.92

5.1 Submitter Information

Applicant:	LimFlow Inc.
Address	3031 Tisch Way 110 Plaza West San Jose, CA 95127
Phone Number:	+1 (888) 478-7705
E-mail:	info@limflow.com
Contact:	Zachary Woodson
Contact e-mail:	zwoodson@limflow.com
Contact Phone Number:	+1 (707) 328-6522
Date Prepared:	20 December 2022

5.2 Proposed Device

Trade Name:	LimFlow Vector
Common name:	Valvulotome
Classification name:	Device, External Vein Stripper Product
Classification:	Class II
Regulation:	21 CFR 870.4885
Product Code:	MGZ

5.3 Predicate Device

Trade Name:	Expandable LeMaitre Valvulotome (ELV)
Common name:	Valvulotome
Classification name:	Device, External Vein Stripper Product
Classification:	Class II
Regulation:	21 CFR 870.4885
Product Code:	MGZ
Premarket Notification:	K132190

Note: This predicate device has not been subject to a recall.

5.4 Device Description

The LimFlow Vector is a single-use medical device designed to cut venous valves during vascular in-situ bypass procedures. The LimFlow Vector consists of a 4Fr intravascular catheter that has a working length of 120cm. It utilizes a deployment mechanism to deploy the self-expanding nitinol cutting basket mounted at distal tip which self-centers in the vessel to prevent the cutting blades from damaging the vessel wall. The size of the cutting basket and cutting blades adjust to the internal diameter of the vein as the LimFlow Vector is being drawn through the vessel. The LimFlow Vector is compatible with 0.018”

standard guide wires. The LimFlow Vector is used in a healthcare facility, such as a catheter lab or hospital. It is in contact with patient tissue for less than 24 hours. The LimFlow Vector is supplied sterile.

5.5 Intended Use/Indications For Use

The LimFlow Vector is intended for the treatment of vascular disorders and more particularly for excising or disrupting venous valves.

5.6 Comparison of Technological Characteristics with the Predicate Device

A comparison of the technological characteristics of the subject device and the predicate device shows the LimFlow Vector to be substantially equivalent to the current marketed predicate device. Equivalence is based on the product performance, design, and intended use. The LimFlow Vector and the predicate device have similar designs, materials of construction, and use ethylene oxide sterilization processes. The LimFlow Vector does not contain a hydrophilic coating and is offered in one 120 cm catheter length versus two shorter (40 or 98 cm) lengths for the predicate device. The LimFlow Vector has a 4 French outer diameter (OD) with a 4.5 mm cutting basket OD versus the 6 French OD predicate with a 9.5 mm cutting basket OD.

5.7 Performance Data

The following tests were performed under the specified testing parameters to support the LimFlow Vector device's substantial equivalence.

Performance Testing, including

- Dimensional verification against product design specifications
- Simulated Use
- Tensile Strength testing of all bond joints
- Flexibility and Kink resistance
- Torque Strength
- Radiopacity
- Corrosion resistance
- Particulate Evaluation
- Luer and Leak Testing
- Shelf-life Testing
- Sterilization Validation
- Packaging Validation

- Biocompatibility – In conformance with the applicable sections of ISO 10993-1, the following testing was performed confirming biocompatibility of the device:
  - Cytotoxicity (ISO 10993-5)
  - Sensitization (ISO 10993-10)
  - Irritation (ISO 10993-10)
  - Acute Systemic Toxicity (ISO 10993-11)
  - Material Mediated Pyrogenicity (ISO 10993-11)
  - Hemolysis (ISO 10993-4)
  - PTT (ISO 10993-4)
  - Complement Activation (ISO 10993-4)
  - Thrombogenicity
- Pre-clinical studies have been performed in the swine and cadaveric model to support substantial equivalence.

5.8 Conclusions

The information submitted in this premarket notification confirms the LimFlow Vector raises no new questions of safety and effectiveness and meets the requirements that are considered essential for its intended use and that the LimFlow Vector is substantially equivalent to the predicate device, the Expandable LeMaitre Valvulotome.