March 18, 2026

LimFlow, Inc.
Haley Ritchie
Staff Regulatory Affairs Specialist
6001 Oak Canyon
Suite 100
Irvine, California 92618

Re: K260188
Trade/Device Name: LimFlow Vector
Regulation Number: 21 CFR 870.4885
Regulation Name: External Vein Stripper
Regulatory Class: Class II
Product Code: MGZ
Dated: January 21, 2026
Received: January 22, 2026

Dear Haley Ritchie:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K260188

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.

510(K) SUMMARY

Date prepared	March 16, 2026
Name	LimFlow, Inc. 6001 Oak Canyon, Suite 100 Irvine, CA 92618
Contact person	Haley Ritchie Staff Regulatory Affairs Specialist (917) 625-8868
Name of Device	LimFlow Vector
Common name	Valvulotome
Regulation name	Device, External Vein Stripper Product
Classification number	21 CFR 870.4885
Product code	MGZ
Regulatory class	II
Predicate device	LimFlow Vector (K221902)
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.
Indications for Use	The LimFlow Vector is intended for the treatment of vascular disorders and more particularly for excising or disrupting venous valves.
Device Modifications	Modified component bond for the LimFlow Vector Device. Strain relief to catheter shaft bond is replaced with a bond between the y-hub to catheter shaft, with no change to the bond specification. Additionally, incremental, non-significant modifications were made to the LimFlow Vector since clearance was granted under K221902.

Comparison of Technological Characteristics with the Predicate Device	The subject device and predicate device consist of the same three primary elements and key features:
	• Primary Elements:
	  ○ Y-connector/hemostasis valve
	  ○ Catheter shaft
	  ○ Cutting basket
	• Key Features:
	  ○ 4Fr sheath compatibility
	  ○ 0.018" guide wire compatibility
	  ○ Cutting basket that self-centers in the vessel
	  ○ Cutting blades that excise or disrupt venous valves

	The subject device and predicate device have the same key dimensions: 4Fr catheter outer diameter (OD), 120 cm catheter length, 4.5mm cutting basket OD, and 0.018" guidewire OD. The difference between the subject and predicate device technological characteristics are as follows: • Replaced strain relief to catheter shaft bond with y-hub to catheter shaft bond. • Removal of stopcock component. • Material change in distal tip, y-hub, basket, luer, and adhesives. • Minor material change in packaging material, and removal of packaging holding card.
Summary of substantial equivalence	There is no change to the intended use, principles of operation, or fundamental scientific technology between the proposed LimFlow Vector and the predicate device. The subject device and predicate device have similar materials of construction and packaging. The following performance tests were conducted on the subject device to demonstrate substantial equivalence: **Biocompatibility** The biocompatibility tests listed below were completed to meet the requirements of ISO 10993-1. • Cytotoxicity • Sensitization • Intracutaneous Reactivity • Acute Systemic Toxicity • Material-Mediated Pyrogenicity • Hemocompatibility (Hemolysis, PTT, Complement Activation) • Platelet and Leukocyte Count • Comparative Surface Assessment The passing results demonstrate that the subject device meets the biological safety requirements per ISO 10993-1. **Non-Clinical Testing** In accordance with the design failure modes and effects analysis, design verification testing was conducted to verify that the modified device continues to meet the design requirements of the product specifications. The following tests were performed on the modified device: • Dimensional Verification and Visual Inspection • Simulated Use • Catheter Bond Strength Test • Flexibility & Kink Test • Torque Test • Leak Test • Corrosion Test Radiopacity and luer fitting tests were leveraged from K221902. Neither animal testing nor clinical testing were required for the determination of substantial equivalence. **Sterilization** The subject device is sterilized using EtO to achieve a sterility assurance level (SAL) of 10^{-6} using a validated sterilization process in accordance with the

	principles of ISO 11135:2014/Amd 1:2018. **Packaging Validation** Packaging validation was conducted in accordance with ASTM F1886/F1886M-16, ASTM F2096-11(2019) and ASTM F88/F88M-21 and ASTM D4169-22. **Conclusion** The LimFlow Vector has the same intended use/indications for use and principles of operation as the predicate. The testing provided supports the LimFlow Vector's substantial equivalence to the predicate device.