May 31, 2025

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

Re: K251376
Trade/Device Name: LimFlow ARC
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: PDU
Dated: May 1, 2025
Received: May 2, 2025

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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,

Jenny R. Katsnelson -S

Digitally signed by Jenny R. Katsnelson -S
Date: 2025.05.31 22:08:50 -04'00'

for Lydia Glaw
Assistant Director
DHT2C: Division of Coronary and Peripheral Intervention 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)*
K251376

Device Name
LinFlow ARC

Indications for Use *(Describe)*
The LimFlow ARC is intended to facilitate placement and positioning of guide wires and catheters within the peripheral vasculature. The LimFlow ARC is not intended for use in the coronary or cerebral vasculature..

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) SUMMARY

Date prepared	May 1, 2025
Name	LimFlow Inc. 6001 Oak Canyon, Suite 100 Irvine, CA 92618
Contact person	Haley Ritchie Senior Regulatory Affairs Specialist
Name of Device	LimFlow ARC
Regulation name	Percutaneous catheter
Classification number	21 CFR 870.1250
Product code	PDU
Regulatory class	II
Predicate device	LimFlow ARC (K221541)
Description	The LimFlow ARC is a single-use device designed to facilitate placement and positioning of guide wires within the peripheral vasculature. The device consists of three primary elements: 1) Cannula, 2) Catheter shaft, and 3) Deployment handle with deployment control slide. The LimFlow ARC is used in a healthcare facility, such as a cardiac catheter lab or hospital. It is in contact with patient tissue for less than 24 hours and is made of materials that are biocompatible. The LimFlow ARC is supplied sterile.
Indications for Use	The LimFlow ARC is intended to facilitate placement and positioning of guide wires and catheters within the peripheral vasculature. The LimFlow ARC is not intended for use in the coronary or cerebral vasculature.
Device Modifications	Incremental, non-significant modifications made to the LimFlow ARC since clearance was granted under K221541.
Comparison of Technological Characteristics with the Predicate Device	The subject device and the predicate device have the same design specifications, principles of operation and fundamental technological characteristics. The subject device and predicate device have similar materials of construction and packaging.
Summary of substantial equivalence	There is no change to the intended use, indications for use, principles of operation, or fundamental technological characteristics between the subject device 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
- Material-Mediated Pyrogenicity
- Platelet and Leukocyte Count
- Acute Systemic Toxicity
- Hemocompatibility (Hemolysis, PTT, Complement Activation)
- Comparative Surface Assessment

Sterilization

Sterilization validation was conducted in accordance ISO 11135:2014/A1:2018.

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.

Non-Clinical Testing

The non-clinical tests listed below were conducted on the subject 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 K221541.

Animal Testing

Animal testing was not required for the determination of substantial equivalence.

Conclusion

The results of all testing conducted on the subject device demonstrates that the subject device is substantially equivalent to the predicate device.