August 31, 2022

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

Re: K221541
Trade/Device Name: LimFlow ARC
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: PDU
Dated: May 26, 2022
Received: May 27, 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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221541

Device Name
LimFlow ARC

Indications for Use *(Describe)*
The LimFlow ARC is intended to facilitate placement and positioning of guidewires 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.

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LimFlow ARC™

510(k) Summary

21 CFR807.92

Submitter Information

Applicant:	LimFlow Inc.
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E-mail:	info@limflow.com
Contact:	Zachary Woodson
Contact e-mail:	zwoodson@limflow.com
Contact Phone Number:	+1 (707) 328-6522
Date Prepared:	26 May 2022

Proposed Device

Trade Name:	LimFlow ARC
Common name:	Percutaneous catheter
Classification name:	Catheter for Crossing Total Occlusions
Classification:	Class II
Regulation:	21 CFR 870.1250
Product Code:	PDU

Predicate Device

Trade Name:	OUTBACK® Elite Re-Entry Catheter
Common name:	Percutaneous catheter
Classification name:	Catheter for Crossing Total Occlusions
Classification:	Class II
Regulation:	21 CFR 870.1250
Product Code:	PDU
Premarket Notification:	K150836

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

Device 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.

Intended Use/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.

Comparison of Technological Characteristics with the Predicate Device

The LimFlow ARC is substantially equivalent to the predicate device based upon the following similarities:

- Both devices are intended to be used to cross chronic total occlusions (CTOs) in peripheral vessels
- Both devices are used in cardiac catheter labs in either a hospital or an office-based lab
- Both devices are advanced to the target occlusion through an indwelling vascular sheath
- Advancement of both devices is monitored by external fluoroscopy
- Both devices have equivalent sizes in terms of outer diameter and working length of the cannula
- Both devices share the same basic design, mechanism of action, and principles of operation
- Both devices share the same sterilization method (EO)

The table below compares the LimFlow ARC (this submission) to the predicate device, the Outback Elite (K150836).

Device Feature	OUTBACK Elite (Predicate)	LimFlow ARC (This Submission)
Device Classification	Class II	Same
Classification Name	Catheter for Crossing Total Occlusions (21 CFR 870.1250)	Same
Device Category	Percutaneous catheter	Same
Indications for Use	The OUTBACK Elite is intended to facilitate placement and positioning of guide wires and catheters within the peripheral vasculature. The OUTBACK Elite is not intended for use in the coronary or cerebral vasculature.	Same
Device Description: Design & Operating Principle	The OUTBACK Elite 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 OUTBACK Elite Re-Entry Catheter is supplied sterile and is available in two usable lengths (80 cm and 120 cm).	Same, except the is available in one usable length (100 cm).
Packaging Contents	One (1) OUTBACK Elite	Same

Device Feature	OUTBACK Elite (Predicate)	LimFlow ARC (This Submission)
Contraindications	The OUTBACK Elite is not intended for use in the coronary or cerebral vasculature.	Same
Where used	Hospital or office-based lab	Same
Technological Characteristics	The OUTBACK Elite consists of three primary elements: 1) 22-gauge nitinol re-entry cannula 2) Catheter shaft 3) Deployment handle with deployment control slide Key features of the OUTBACK Elite Re-Entry Catheter include: - 6F sheath compatibility - 0.014'' guide wire compatibility - Hydrophilic coating along the entire length of the catheter - Ergonomic Handle - Radiopaque markers at the distal end that enables lumen orientation under fluoroscopy	Same, except the LimFlow ARC does not contain a hydrophilic coating.
Guide wire compatibility	The OUTBACK Elite is recommended for use with the following guide wires: Cordis ATW 0.014" Cordis STABILIZER® Plus 0.014" Cordis STABILIZER® XS 0.014" 0.014" Boston Scientific Platinum Plus 0.014" Boston Scientific Choice Extra Support 0.014" Boston Scientific Mailman 0.014" Boston Scientific Luge 0.014"	The LimFlow ARC is recommended for use with the following crossing guide wires: Boston Scientific Thruway 0.014" Medtronic Nitrex 0.014" Terumo Runthrough 0.014"
Duration of use per ISO 10993-1	Externally communicating medical device in contact with circulating blood for ≤ 24 hrs.	Same
Target Population	Patients requiring placement and positioning of guide wires and catheters in the peripheral vasculature.	Same
Anatomical Sites	Cardiovascular system	Cardiovascular system
Key Dimensions	Catheter OD: 6 French Catheter Length: 80 cm or 120 cm Cannula Throw: 8 mm Cannula Opening: 22-gauge	Catheter OD: Same Catheter Length: 100 cm Cannula Throw: 10 mm Cannula Opening: Same
Materials	Medical grade metals and polymers	Same
Sterilization Method	Ethylene Oxide	Same
Performance & Test data	• Biocompatibility per 21 CFR Part 58 and per ISO 10993-1, including: • Dimensional and Functional Testing, including: o Device Joint Tensile Strength o Catheter Torqueability o Device Joint Torque to Failure • Packaging Validation • Sterilization Validation	Same

Performance Data

The following performance data were provided to establish that the LimFlow ARC does not raise new questions of safety or effectiveness compared o the predicated OUTBACK Elite cleared under K150836:

Biocompatibility Testing

Biocompatibility testing was performed on finished and sterilized LimFlow ARC in compliance with the U.S. Food and Drug Administration Good Laboratory Practice (GLP) regulations set forth in 21 CFR Part 58 and ISO 10993-1 Biological evaluation of medical devices – Part 1. Biocompatibility testing included the following:

- Cytotoxicity
- Hemolysis
- Complement Activation
- Intracutaneous Irritation
- Maximum Sensitization
- Acute Systemic Toxicity
- Pyrogenicity
- Partial Thromboplastin Time
- Thrombogenicity

Device Dimensional and Functional Testing

- Dimensional Verification
- Device Joint Tensile Strength
- Catheter Torqueability
- Device Joint Torque to Failure
- Flex / Kink Testing
- Simulated Use

Packaging and Sterilization Testing

- Packaging Validation
- Sterilization Validation

Conclusions

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