August 9, 2022

LimFlow Inc.
% Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K222083
Trade/Device Name: LimFlow V-Ceiver
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy catheter
Regulatory Class: Class II
Product Code: MMX
Dated: July 14, 2022
Received: July 15, 2022

Dear Prithul Bom:

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,

Gregory O'Connell
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)*
K222083

Device Name
LimFlow V-Ceiver™

Indications for Use *(Describe)*
The LimFlow V-Ceiver™ is intended for use in the cardiovascular system to manipulate and retrieve guidewires specified in the IFU.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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
K222083

Date Prepared:	15 June 2022
Company	LimFlow Inc. 3031 Tisch Way 110 Plaza West San Jose, CA 95127
Contact:	Zachary Woodson VP of Regulatory Affairs & Quality Phone: +1 707-328-6522 Email: zwoodson@limflow.com
Device Trade Name:	LimFlow V-Ceiver
Device Common Name:	Embolectomy Catheter
Device Classification:	Device, Embolectomy Catheter Product Code: MMX 21 CFR 870.5150 Class II Review Panel: Cardiovascular Devices
Predicate Device:	K112185, CloverSnare™[1] Vascular Retrieval Snare, originally manufactured by Cook Incorporated
Description of the Device:	The LimFlow V-Ceiver consists of an intravascular catheter which incorporates a nitinol basket (the "Snare") at its distal tip. The nitinol basket has an outer diameter of 6 mm. The catheter has a built-in coaxial sheathing system and incorporates radiopaque markers at the distal tip on either end of the basket for added visibility. The catheter if compatible with 4 Fr introducer sheaths and has a working length of 100 cm.
Intended Use / Indication for Use:	The LimFlow V-Ceiver is intended for use in the cardiovascular system to manipulate and retrieve guidewires specified in the IFU.
Technological Characteristics:	A comparison of the technological characteristics of the subject device and the predicate device shows the LimFlow V-Ceiver to be substantially equivalent to the current marketed predicate device.

[1] CloverSnare™ is the commercial name of the device that was approved under the name "FourSnare™" per 510(K) reference K112185

Equivalence is based on the product performance, design, and intended use. The LimFlow V-Ceiver and the predicate device have similar materials of construction, dimensional specifications, designs, and sterilization process.

Performance Tests (Non-Clinical):

No performance standards have been established under section 514, performance standards, of the Food, Drug and Cosmetic Act for these devices. A series of testing was conducted in accordance with protocols based on requirements outlined in guidance and industry standards and the below were shown to meet the acceptance criteria that were determined to demonstrate substantial equivalence.

The following tests were performed under the specified testing parameters to support the LimFlow V-Ceiver device substantial equivalence.

<u>Performance Testing, including:</u>

- Tensile Strength - In conformance with the applicable sections of ISO 10555-1, joint strengths were evaluated and met the predetermined acceptance criteria.
- Leak Testing - In conformance with the applicable sections of ISO 10555-1, leak testing was performed and met the predetermined acceptance criteria.
- Simulated Use - Testing demonstrated the device can grasp guidewires during simulated clinical use, meeting the predetermined acceptance criteria.
- Kink Testing – Testing demonstrated the catheter would not kink during clinical use, meeting the predetermined acceptance criteria.
- Opening and Closing Basket Width – Testing demonstrated the basket could be opened and closed, meeting the predetermined acceptance criteria.
- Retraction Force – Testing demonstrated that the snare can be retracted with a clinically acceptable amount of force, meeting the predetermined acceptance criteria.
- Radiopacity – Testing confirmed acceptable radiopacity during clinical use.
- Corrosion – Testing confirmed acceptable corrosion performance.

- Packaging Validation - Testing demonstrated the packaging system can maintain package integrity and met the predetermined acceptance criteria.
- 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)
  - Thromboresistance (ISO 10993-4)

A pre-clinical study was performed in an acute swine model to evaluate the performance of the LimFlow V-Ceiver. Snaring of various guidewires was performed to demonstrate the device is appropriate with the stated indications. Furthermore, thrombogenicity was evaluated and confirmed to be acceptable.

Substantial Equivalence: Based on the Indication for Use, design, safety, and performance testing, the LimFlow V-Ceiver device met the requirements for its intended use and is substantially equivalent to the predicate device.

Conclusion: The result of all testing demonstrates that the LimFlow V-Ceiver device is substantially equivalent to the predicate device.