



Food and Drug Administration
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November 22, 2016

Inari Medical, Inc.
Mr. Eben Gordon
Vice President, Regulatory Affairs & Quality Assurance
9272 Jeronimo Road, Suite 124
Irvine, CA 92618

Re: K162970

Trade/Device Name: FlowTrieve Retrieval/Aspiration System
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: DXE
Dated: October 21, 2016
Received: October 24, 2016

Dear Mr. Gordon:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely,


Brian D. Pullin -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K162970

Device Name

FlowTrieve Retrieval/Aspiration System

Indications for Use (Describe)

The FlowTrieve Retrieval/Aspiration System consists of the FlowTrieve Catheter, Aspiration Guide Catheter, and Retraction Aspirator. The FlowTrieve Retrieval/Aspiration System is indicated for:

- The non-surgical removal of emboli and thrombi from blood vessels.
- Injection, infusion, and/or aspiration of contrast media and other fluids into or from a blood vessel.

The FlowTrieve Retrieval/Aspiration System is intended for use in the peripheral 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.

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510(K) SUMMARY

Date prepared	November 13, 2016
Name	Inari Medical, Inc. 9272 Jeronimo Road, Suite 124 Irvine, CA 92618 949.600.8433 x114
Contact person	Eben Gordon Vice President, Regulatory Affairs & Quality Assurance
Trade name	FlowTrieveer Retrieval/Aspiration System
Common name	Embolectomy catheter
Regulation Name	Embolectomy catheter
Classification number	21 CFR 870.5150
Product code	DXE
Regulatory class	II
Predicate devices	Inari Medical Infusion Aspiration Catheter System (K143563)
Description	<p>The FlowTrieveer Retrieval/Aspiration System is a single-use over-the-wire catheter-based system for the minimally invasive treatment of thromboemboli in the peripheral vasculature. The system is comprised of three main components packaged separately:</p> <ul style="list-style-type: none">• Aspiration Guide Catheter (AGC)• FlowTrieveer Catheter (available in 3 sizes: 6-10 mm, 11-14 mm, and 15-18 mm)• Retraction Aspirator <p>The FlowTrieveer Catheter is inserted through the Aspiration Guide Catheter and advanced to the thrombus. Self-expanding wireform disks are deployed to engage thrombus by retracting the outer delivery catheter. The hand-lever operated Retraction Aspirator simultaneously aspirates fluids and retracts the FlowTrieveer Catheter with thrombus into the Aspiration Guide Catheter to capture clot and restore blood flow.</p>
Device Modifications	<p>The change to the FlowTrieveer Retrieval/Aspiration System allows the removal of the FlowTrieveer Catheter from the patient without the simultaneous removal of the Aspiration Guide Catheter. The modifications being implemented are:</p> <p><u>Retraction Aspirator Tubing Set</u></p> <ol style="list-style-type: none">1. The checkvalve in the tubing arm is replaced with the clot reservoir. The former in-line checkvalve component is now integrated into the clot

reservoir cap.

2. The connection to the AGC is achieved via a quick-release coupling rather than a Luer connection.

Aspiration Guide Catheter

3. Increasing the side port tubing inner diameter from 0.098" to 0.188".
4. Replacing the stopcock with an on/off clamp and the larger lumen quick-release coupling.
5. Opening the hub's tubing connection lumen diameter from 0.096" to 0.235" to accommodate the larger inner diameter tubing.

New Aspiration Guide Catheter Components

6. Flush Port Adapter – Luer female connector on one end and a quick-release coupling on the other for attachment to the AGC.
7. Hub Valve Insert - Inserted into the AGC hub to open the hemostasis valve as the FlowTrieve Catheter is drawn through it.
8. Aspiration Insert – Seals on the guidewire and in the hub to allow a vacuum to transport any thrombus (and blood) to the clot reservoir.

Indications for Use

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- The non-surgical removal of emboli and thrombi from blood vessels.
- Injection, infusion, and/or aspiration of contrast media and other fluids into or from a blood vessel.

The FlowTrieve Retrieval/Aspiration System is intended for use in the peripheral vasculature.

Summary of substantial equivalence

There is no change of intended use or fundamental scientific technology between the proposed and predicate devices.

Non-Clinical Testing

In accordance with the Design Failure Modes and Effects Analysis, verification and validation testing were identified to support the safety and effectiveness of the modified FlowTrieve Retrieval/Aspiration System. This testing demonstrated compliance with relevant product specifications. These tests included:

- Visual & Dimensional Inspections
- Leakage Testing: Guide Catheter Hemostasis Valve and Devices
- Air Leakage from Guide Catheter Hemostasis Valve During Syringe Pullback
- Retraction Testing: Retraction Aspirator
- Check Valve & Vent Plug Testing: Tube set
- Leakage Verification: Tube Set, Clot Reservoir
- Valve Cracking Pressure: Clot Reservoir
- Simulated use Track and Tensile: Guidewire Compatibility
- Simulated use Track and Tensile: Flush Port, Guide Catheter, Tube Set
- Vacuum Testing: Guide Catheter, Clot Reservoir, Tube Set
- Torque Testing: Clot Reservoir Luer Activated Valve

- Clot Burden: Clot Reservoir
- Valve Dilator Insertion Force: Guide Catheter
- Corrosion Resistance: Clot Reservoir

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

Conclusion

Test results demonstrated that all acceptance criteria were met; therefore, the device conforms to established product specifications and intended use. Based upon the same intended use and principle of operation, technology, and non-clinical testing, it is concluded that the modified FlowTrieve Retrieval/Aspiration System is substantially equivalent to the predicate device.