June 1, 2023

Innova Vascular, Inc.
Ryan Kenney
Director, Regulatory Affairs
15375 Barranca Parkway, B-101
Irvine, California 92618

Re: K223929
Trade/Device Name: Laguna Clot Retriever™ System and Malibu Aspiration Catheter™ System (Laguna Thrombectomy System)
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: QEW, KRA
Dated: May 2, 2023
Received: May 4, 2023

Dear Ryan Kenney:

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 Eleni Whatley -S Digitally signed by Eleni Whatley -S Date: 2023.06.01 20:54:07 -04'00'

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)*
K223929

Device Name
Laguna Clot Retriever™ System and Malibu Aspiration Catheter™ System (Laguna Thrombectomy System)

Indications for Use *(Describe)*
The Laguna Thrombectomy 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 Laguna Thrombectomy System is intended for use in the peripheral vasculature.

The Malibu Aspiration Catheter™ 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 Malibu Aspiration Catheter™ 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:	June 1, 2023
Device Classification Name:	Peripheral Mechanical Thrombectomy with Aspiration
Device Name:	Laguna Clot Retriever™ System and Malibu Aspiration Catheter™ System (Laguna Thrombectomy System)
Applicant:	Innova Vascular, Inc. 15375 Barranca Pkwy Ste B101 Irvine, CA 92618
Applicant Contact:	Ryan Kenney Director, Regulatory Affairs
Regulation Number:	870.5150
Product Code(s):	QEW, KRA
Regulation Medical Specialty:	Cardiovascular
Review Panel:	Cardiovascular
Predicate Device:	FlowTriever Retrieval/Aspiration System (K211013)

Device Description:

The Laguna Clot Retriever™ System is a single use, sterile, non-pyrogenic medical device designed for use in the peripheral vasculature. The Laguna Clot Retriever™ System is intended be used in conjunction with the Malibu Aspiration Catheter™ System. The combined use of the Laguna Clot Retriever™ System and Malibu Aspiration Catheter™ System is referred to as the Laguna Thrombectomy System.

The Laguna Clot Retriever™ is used to engage and retrieve emboli and thrombi into the Malibu Aspiration Catheter™. The Laguna Clot Retriever™ is designed with a flexible pusher attached to a distal self-expanding, laser cut, closed cell design Nitinol structure. The self-expanding portion is delivered inside a delivery sheath. The flexible pusher is designed with stainless steel reinforcement and a polymer. The retriever head is designed with and without radiopaque body markers. The retriever head designed with radiopaque body markers is intended to visualize the expansion and collapse of the Laguna Clot Retriever™.

The Malibu Aspiration Catheter™ System is a single use, sterile, non-pyrogenic medical device designed for use in the peripheral vasculature. The Malibu Aspiration Catheter™ System is intended be used independently and in conjunction with the Laguna Clot Retriever™ System.

The Malibu Aspiration Catheter™ is intended for retrieving thrombi or emboli and/or infusing fluids into the peripheral vasculature. The Malibu Aspiration Catheter™ is designed with a single lumen and comprised of tubes for aspiration and infusion connected proximally to its hub. Two-way flow control valves are located at the end of aspiration and infusion tubes, respectively. The aspiration tube can be connected to a locking vacuum syringe via its two-way valve. Similarly, the infusion tube can be connected to a syringe to infuse fluids through the catheter. The Malibu Aspiration Catheter™ is designed with a radiopaque marker band at the distal tip for fluoroscopic visualization. In addition, the Malibu Aspiration Catheter™ is also available with a second marker band located proximally to the distal marker band. The Malibu Aspiration Catheter™ is supplied with a dilator and a 60cc locking

syringe. The Malibu Aspiration Catheter™ incorporates a metallic reinforcement made of stainless steel, an inner liner made of polytetrafluoroethylene, and polymeric jacket material having gradient softness. The distal segment of the Malibu Aspiration Catheter™ is coated with a hydrophilic coating to optimize lubricity and reduce friction.

Indications for Use Statement:
The Laguna Thrombectomy 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 Laguna Thrombectomy System is intended for use in the peripheral vasculature.

The Malibu Aspiration Catheter™ 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 Malibu Aspiration Catheter™ System is intended for use in the peripheral vasculature.

Comparison of Technological Characteristics:

	FlowTriever Retrieval/Aspiration System	Laguna Clot Retriever™ System/Malibu Aspiration Catheter™ System (Laguna Thrombectomy System)
	Predicate Device	Subject Device
510(k) Number:	K211013	K223929
Product Code(s):	QEW, KRA	Same as K211013
Indications for Use Statement:	The FlowTriever 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 FlowTriever Retrieval/Aspiration System is intended for use in the peripheral vasculature and for the treatment of pulmonary embolism. Triever Catheters (Triever 16, Triever 20, Triever 20 Curve, and Triever 24) are also intended for use in treating clot in transit in the right atrium but not in conjunction with FlowTriever Catheters.	The Laguna Thrombectomy 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 Laguna Thrombectomy System is intended for use in the peripheral vasculature. The Malibu Aspiration Catheter™ 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 Malibu Aspiration Catheter™ is intended for use in the peripheral vasculature
FlowTriever Catheter/Laguna Clot Retriever™ System – Dimensional		
Size (Vessel Diameter Range)	S (6 – 10 mm) M (11 – 14 mm) L (15 – 18 mm) XL (19 – 25 mm)	10 mm (≥ 6 mm) 14 mm (≥ 10 mm)
Outer Diameter	4 mm	10 mm: 3.1 mm 14 mm: 4 mm

	FlowTriever Retrieval/Aspiration System	Laguna Clot Retriever™ System/Malibu Aspiration Catheter™ System (Laguna Thrombectomy System)
	Predicate Device	Subject Device
Usable Length	115 cm	10 mm: 127 cm 14 mm: 119 cm
Guidewire Compatibility	0.035”	Same
FlowTriever Catheter/Laguna Clot Retriever™ System – Material		
Self-Expanding Nitinol Retriever	Yes	Same
Polymeric Delivery Sheath	Yes	Same
FlowTriever Catheter/Laguna Clot Retriever™ System – Supplied		
Non-Pyrogenic	Yes	Same
Sterile	Ethylene Oxide	Same
Single Use	Yes	Same
Triever Aspiration Catheter/Malibu Aspiration Catheter™ System – Dimensional		
Outer Diameter	16 Fr 20 Fr 24 Fr	12 Fr 16 Fr 20 Fr 24 Fr
Usable length	16 Fr: 107 cm 20 Fr: 90 cm 24 Fr: 90 cm	12 Fr: 115 cm 16 Fr: 107 cm 20 Fr: 100 cm 24 Fr: 90 cm
Guidewire Compatibility	0.035”	Same
Triever Aspiration Catheter/Malibu Aspiration Catheter™ System – Material		
Polymeric Jacket with Multiple Durometers	Yes	Same
Metallic Reinforcement	Yes	Same
Liner	Yes	Same
Triever Aspiration Catheter/Malibu Aspiration Catheter™ System – Packaged With		
Dilator	Yes	Same
Syringe	Yes	Same

	FlowTriever Retrieval/Aspiration System	Laguna Clot Retriever™ System/Malibu Aspiration Catheter™ System (Laguna Thrombectomy System)
	Predicate Device	Subject Device
Triever Aspiration Catheter/Malibu Aspiration Catheter™ System – Supplied		
Non-Pyrogenic	Yes	Same
Sterile	Ethylene Oxide	Same
Single Use	Yes	Same

Sterilization:
The Laguna Clot Retriever™ System and the Malibu Aspiration Catheter™ System are ethylene oxide sterilized. The Laguna Clot Retriever™ System and the Malibu Aspiration Catheter™ System met the requirements for ethylene oxide and ethylene chlorohydrin residuals per ISO 10993-7:2008/Amd1:2019. In addition, the Laguna Clot Retriever™ System and the Malibu Aspiration Catheter™ System met the requirements for bacterial endotoxin per AAMI/ANSI ST72:2019.

Shelf-Life:
The Laguna Clot Retriever™ System and the Malibu Aspiration Catheter™ System have a shelf-life of one (1) year.

Biocompatibility:
Biocompatibility was conducted for the Laguna Clot Retriever™ System and the Malibu Aspiration Catheter™ System to meet the requirements of ISO 10993-1:2018 and Guidance for Industry and Food and Drug Administration Staff, Use of International Standard ISO 10993-1. The following biological endpoints were evaluated:

- Cytotoxicity
- Sensitization
- Intracutaneous Reactivity
- Acute Systemic Toxicity
- Material-Mediated Pyrogenicity
- Hemocompatibility
    - Hemolysis
    - Complement Activation
    - Thrombogenicity

Performance Data – Bench:
The Laguna Clot Retriever™ System was evaluated for the following:

- Dimensional Verification
- Visual Inspection
- Tensile Strength
- Turns to Failure
- Coating Integrity
- Corrosion Resistance
- Kink to Failure
- Liquid Leakage
- Air Leakage into Hub Assembly
- Radial Force
- Unsheathing and Resheathing Force
- Unsheathing and Resheathing Integrity
- Luer Fittings

The Malibu Aspiration Catheter™ System was evaluated for the following:

- Dimensional Verification
- Visual Inspection
- Tensile Strength
- Torque Transmission
- Turns to Failure
- Coating Integrity
- Corrosion Resistance
- Kink to Failure
- Liquid Leakage
- Air Leakage into Hub Assembly
- Lumen Collapse
- Luer Fittings

The Laguna Thrombectomy System was evaluated for the following:

- Particulate Evaluation
- Simulated Use
- Usability

Performance Data – Animal:
The radiopacity and safety of the Laguna Thrombectomy System was evaluated at acute and chronic time points in a porcine model and was conducted in accordance with 21 CFR Part 58 for Good Laboratory Practice (GLP) for Non-Clinical Laboratory Studies.

Performance Data – Clinical:
A determination of substantial equivalence is based upon successful completion of performance data – bench and animal.

Conclusion:
The Laguna Thrombectomy System and Malibu Aspiration Catheter™ System are substantially equivalent to the FlowTriever Retrieval/Aspiration System.