January 21, 2026

Verge Medical, Inc.
c/o Rey Jacinto
Principal Regulatory Consultant
Bridge City Regulatory, LLC
5331 S Macadam Ave.
Suite 258, Pmb #708
Portland, Oregon 97239

Re: K253730
Trade/Device Name: RoVo Mechanical Thrombectomy System
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: QEW
Dated: November 24, 2025
Received: November 24, 2025

Dear Rey Jacinto:

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,

GREGORY W. O'CONNELL -S

Digitally signed by GREGORY W. O'CONNELL -S
Date: 2026.01.21 14:42:32 -05'00'

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K253730

Device Name
RoVo Mechanical Thrombectomy System

Indications for Use *(Describe)*
The RoVo Mechanical Thrombectomy System is indicated for the removal of soft emboli and thrombi from vessels 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.

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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510(k) Summary
per 21 CFR 807.87(h) and 21 CFR 807.92

747 Camden Avenue, Campbell, CA 95008 USA

RoVo Mechanical Thrombectomy System

510(k):	K253730
Date Prepared:	24 November 2025
Submitter:	Verge™ Medical, Inc. 747 Camden Avenue Suite A Campbell, CA 95008, USA
Contact Person:	Michael Buck, CEO Tel: 844-352-7411
Device Name:	RoVo Mechanical Thrombectomy System
Common Name:	Peripheral Mechanical Thrombectomy With Aspiration
Predicate Device:	RoVo Mechanical Thrombectomy System, K220780
Reference Device:	Performa Diagnostic Catheter, K943739
Device Classification:	Class II per 21 CFR §870.5150, Embolectomy Catheter
Product Code:	QEW

Intended Use / Indications for Use:
The RoVo Mechanical Thrombectomy System is indicated for the removal of soft emboli and thrombi from vessels in the peripheral vasculature.

Device Description:
The RoVo Mechanical Thrombectomy System (RoVo System) is a single use, sterile device that is indicated for the removal of soft emboli and thrombi from vessels in the peripheral vasculature. The system consists of a RoVo Driver, a RoVo Locking Aspiration Syringe, and a RoVo Catheter.

The RoVo Catheter is maneuvered under fluoroscopic observation to the location of the target thromboemboli utilizing the operator's preferred vascular access procedure. Once in the desired location, the RoVo Driver handpiece with the RoVo Locking Syringe is attached to the catheter. Squeezing the trigger of the handpiece rotates the distal tip of the RoVo Driver, which in turn rotates the RoVo Catheter. Rotation does not happen when the trigger is released. Aspiration of the emboli/thrombi happens upon opening the stopcock to the vacuum in the Locking Syringe, independent of the catheter rotation. During aspiration, the operator can continue to pull the trigger and move the catheter as needed to capture the target thromboemboli.

Comparison with Predicate Device:
The subject device is substantially equivalent to the Predicate RoVo System (K220780) based on the use of the same or similar materials, similar design, the same fundamental operating principles, and the same indications for use. The subject RoVo System utilizes a similar, but different commercially available off-the-shelf catheter model in place of its previously cleared catheter. The catheter is private labeled by the original catheter manufacturer for commercial use with the RoVo System.

Device Characteristics	Subject Device	Predicate Device
Indications for Use	The RoVo Mechanical Thrombectomy Device is indicated for the removal of soft emboli and thrombi from vessels in the peripheral vasculature.	Same
Product Code	QEW	Same
Regulation Number	21 CFR 870.5150 Embolectomy Catheters	Same
Classification	II	Same
Prescription/Over-the-Counter Use	Prescription Only	Same
Single Use Only	Yes	Same
RoVo System Components	RoVo Driver RoVo Catheter RoVo Locking Aspiration Syringe	Same

RoVo Catheter Dimensions (OD, Length)	6F, 100cm	Same
Guidewire Compatibility	Up to 0.038”	Same
Provided Sterile	Yes	Same
Sterilization Method	Ethylene Oxide (EO)	Same
Shelf Life	12 Months	Same
System Materials	Commonly used medical grade plastics and metals	Similar

Non-Clinical Performance Data:

The RoVo System was evaluated for the following in-vitro and performance bench testing to confirm the performance characteristics as compared to the product performance requirements:

- Shelf Life
- Trackability
- Torque Transmission
- Kink Resistance
- Air Leak Resistance
- Tensile Strength
- Kink Resistance
- Simulated Use Testing

Substantial Equivalence Conclusion:

The performance bench tests demonstrated that the RoVo System met all pre-defined acceptance criteria. This testing, when considered with biocompatibility, packaging, and sterilization conducted by the original manufacturer of the subject catheter, demonstrate that the subject device is substantially equivalent to the legally marketed predicate device.