March 31, 2023

2MG, Inc
% Kelli Anderson
Principal Consultant
Tech2Med, LLC
6450 Old Darby Trl NE
Ada, Michigan 49301

Re: K220780
Trade/Device Name: ROVO Mechanical Thrombectomy Device
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: QEW
Dated: February 24, 2023
Received: February 24, 2023

Dear Kelli Anderson:

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 W. O'connell -S
Digitally signed by Gregory W. O'connell -S
Date: 2023.03.31 09:10:21 -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)*
K220780

Device Name
ROVO Mechanical Thrombectomy Device

Indications for Use *(Describe)*
The ROVO Mechanical Thrombectomy Device 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.

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**510(K) SUMMARY**



**(a)(1). Submitted By:**

2MG, Inc
176 Nanagosa Trail
Suttons Bay, MI 49682
United States of America

**Contact Person:**

Kelli Anderson
Principal Regulatory Consultant
Office – (574) 527-9214

**Date:** March 16, 2022

**(a)(2). Proprietary Name:** Rovo Mechanical Thrombectomy Device

**Common Name(s):** Peripheral Mechanical Thrombectomy with Aspiration

**Classification Name:** 21 CFR 870.5150: Embolectomy catheter

**Regulatory Class:** Class II
**Product Code:** QEW

**(a)(3). Primary Predicate Device:** K113757 – Aspire MAX Aspiration Catheter
**Secondary Predicate Device:** K202218 – Zelante DVT ClotHunter Helical Rotation Device
**Reference Devices:** K121051 and K132409 – Merit Medical Concierge Catheters

**(a)(4). Device Description**

The ROVO Mechanical Thrombectomy Device is indicated for the removal of soft emboli and thrombi from vessels in the peripheral vasculature. It consists of a ROVO Driver, a ROVO Locking Aspiration Syringe, and a ROVO Catheter. The ROVO Driver handpiece was designed to work with an off-the-shelf catheter manufactured by Merit Medical Systems, Inc (K121051 and K132409) and an off-the-shelf locking aspiration syringe (K163597) also manufactured by Merit Medical Systems, Inc. Both the catheter and syringe are private labeled with the ROVO system name.

The ROVO Catheter is maneuvered under fluoroscopic observation to the location of the target thromboemboli utilizing the surgeon'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 of the handpiece rotates the distal tip of the ROVO Driver. This rotation ensures the thromboemboli is loosened and the catheter tip is fully exposed to the vessel to completely capture and aspirate the thromboemboli. Rotation does not happen when the trigger is released. Aspiration of the emboli/thrombi happens upon release of the Locking Syringe, independent of the catheter rotation. During aspiration, the surgeon can continue to pull the trigger and move the catheter as needed to capture the target thromboemboli.

**(a)(5). Indications for Use**

The ROVO Mechanical Thrombectomy Device is indicated for the removal of soft emboli and thrombi from vessels in the peripheral vasculature.

**(a)(6). Technological Characterizes**

The subject devices included in ROVO Mechanical Thrombectomy Device are similar to predicate devices in material, size, and have the similar indications for use.

**(b)(1). Substantial Equivalence: - Non-Clinical Evidence Performance Data**

2MG has leveraged testing completed by Merit Medical Systems for the general performance, sterility and packaging of the compatible Concierge Catheter (K121051 and K132409). Overall performance of the ROVO Driver in combination with the off-the-shelf catheter and syringe components were evaluated for:

- Shelf-Life Validation
- Particulate Testing
- Biological Evaluation per ISO 10993-1:2018
- Small-bore Connector Testing per ISO 80369-7:2021
  - Dimensional Requirements
  - Leakage by Pressure Decay
  - Subatmospheric Pressure Air Leakage
  - Stress Cracking per ISO 80369-20
  - Resistance to Separation from Axial Load Test
  - Resistance to Separation from Unscrewing
  - Resistance to Overriding
- Trackability
- Torque Transmission
- Kink Resistance
- Air Leak Resistance
- Tensile Strength
- Mechanical Testing on Handpiece
- Packaging per ISO 11607-1:2020
- Sterilization per AAMI and ISO standards
- Rotational Safety
- Simulated Use Testing

**(b)(2). Substantial Equivalence: - Clinical Evidence**

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

**(b)(3). Substantial Equivalence – Conclusions**

The ROVO Mechanical Thrombectomy Device utilizes an off-the-shelf catheter and aspiration syringe from Merit Medical Systems, Inc.. Based on the indications for use, technological characteristics, and safety and performance testing, the ROVO Mechanical Thrombectomy Device has been shown to be appropriate for its intended use and is considered to be substantially equivalent to the Aspire MAX Aspiration Catheter (K113757), the ZelanteDVT ClotHunter Helical Rotation Device (K202218) and the Concierge Guiding Catheter (K121051 and K132409).