



July 3, 2025

Aveera Medical, Inc.  
Christopher Chapek  
Director of Regulatory and Quality  
929 Calle Negocio, Suite A  
San Clemente, California 92673

Re: K250105  
Trade/Device Name: Boomerang Valvulotome  
Regulation Number: 21 CFR 870.4885  
Regulation Name: External vein stripper  
Regulatory Class: Class II  
Product Code: MGZ  
Dated: January 8, 2025  
Received: January 15, 2025

Dear Christopher Chapek:

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

**Rohini Retarekar -S**

for Carmen Gacchina Johnson, Ph.D.  
Assistant Director  
DHT2B: Division of Circulatory Support,  
Structural, and Vascular Devices  
OHT2: Office of Cardiovascular Devices  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)  
K250105

Device Name  
Boomerang™ Valvulotome

Indications for Use (Describe)

The Boomerang™ Valvulotome is intended for the treatment of vascular disorders and more particularly for excising or disrupting venous valves.

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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## Boomerang™ Valvulotome 510(k) Summary K250105

### 1.1 Submitter Information

Applicant: Aveera Medical, Inc.  
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Contact: Chris Chapek  
Director of Regulatory and Quality  
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Contact Phone: (440) 567-1793  
Date Prepared: 08 January 2025

### 1.2 Proposed Device

Trade Name: Boomerang™ Valvulotome  
Common Name: Valvulotome  
Classification Name: Device, External Vein Stripper  
Classification: Class II  
Regulation: 21 CFR Part 870.4885  
Product Code: MGZ

### 1.3 Predicate Device

Trade Name: Expandable Lemaitre Valvulotome (ELV)  
Common Name: Valvulotome  
Classification Name: Device, External Vein Stripper  
Classification: Class II  
Regulation: 21 CFR Part 870.4885  
Product Code: MGZ  
Premarket Notification: K132190

### 1.4 Device Description

The Boomerang™ Valvulotome is a sterile, single-use, non-coated intravascular catheter designed to disrupt or cut venous valves. Both models of the Boomerang™ Valvulotome consist of a flexible 4F catheter shaft, with a working length of either 80cm (BMGVT080) or 125cm (BMGPVT125). Both models utilize a self-expanding nitinol basket with shielded blades that is mounted at the distal end of the catheter which self-centers in the vessel to prevent the blades from damaging the vessel wall. When deployed, the size of the basket adjusts to the internal diameter of the vein as the device is tracked through the vessel. The Boomerang™ Valvulotome is compatible with standard 0.018" vascular guidewires. The device is used by a physician in a healthcare facility such as a hospital or catheterization lab. The device is in contact with the patient for a short duration (< 24hrs.)

## 1.5 Intended Use / Indications for Use

The Boomerang™ Valvulotome is intended for the treatment of vascular disorders and more particularly for excising or disrupting venous valves.

## 1.6 Comparison of the Technological Characteristics with the Predicate Device

A comparison between the technological characteristics of the proposed device and the predicate device, including materials of construction, design, and mechanism of action, show that the Boomerang™ Valvulotome is substantially equivalent to the currently marketed predicate device, the Expandable Lemaitre Valvulotome. Both devices are deployed using a luer hub at the proximal end of the catheter. Both devices use self-centering, self-sizing expandable nitinol baskets with blades that are intended to engage and disrupt competent venous valves. The Boomerang™ Valvulotome is offered in two lengths, 80cm and 125cm, compared to the predicate device which is offered in two lengths, 40cm and 98cm. The Boomerang™ Valvulotome shaft is 4 French outer diameter and the basket is 5mm outer diameter, compared to the 4 French shaft outer diameter and 9.5mm basket outer diameter of the predicate device. Both devices are sterilized using Ethylene Oxide (EO).

## 1.7 Performance Data

The following performance testing was completed under specified test conditions to support a determination of substantial equivalence for the Boomerang™ Valvulotome:

- Dimensional Measurements and Verification
- Tensile Strength Testing of all Bonds
- Flexibility
- Torque Strength
- Radiopacity
- Simulated Use
- Corrosion Resistance
- Luer Flush Testing
- Distribution Testing
- Sterilization Validation
- Packaging Validation
- Biocompatibility Evaluation
  - Including: Cytotoxicity (ISO 10993-5), Sensitization (ISO 10993-10), Irritation (ISO 10993-23), 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), Platelet and Leukocyte Count Assay (ISO 10993-4)
- Cadaveric studies

## 1.8 Conclusion

The information supplied in this premarket notification confirms that the Boomerang™ Valvulotome has the same intended use as the legally marketed predicate device. The

performance testing data demonstrates that the Boomerang™ Valvulotome is substantially equivalent to the legally marketed predicate device.