April 27, 2020

DeVoro Medical, Inc.
% Roberta Hines
Regulatory Consultant
Northwest Clinical Research Group, Inc.
19836 NE 125th Place
Woodinville, Washington 98077

Re: K200101
Trade/Device Name: WOLF Thrombectomy V System
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: QEW
Dated: March 30, 2020
Received: March 31, 2020

Dear Ms. Hines:

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 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200101

Device Name
Wolf Thrombectomy V System

Indications for Use *(Describe)*
The WOLF Thrombectomy V System is indicated for the nonsurgical removal of emboli and thrombi from arterial and venous blood 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.

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DeVoro Medical

510(k) SUMMARY

DeVoro Medical, Inc. WOLF Thrombectomy™ V System

K200101

General Company Information

Name:	DeVoro Medical, Inc.
Address:	48389 Fremont Blvd., Suite 114 Fremont, CA 94538, USA
Contact:	Roberta Hines, Regulatory Consultant
Telephone:	425-766-0308
Email:	rhines@nwcrg.com

Date Prepared

March 30, 2020

General Device Information

Product Name: WOLF Thrombectomy™ V System
Common Name: Embolectomy Catheter
Classification: Catheter, Embolectomy (21 CFR 870.5150, Product Code: QEW)

Predicate Devices

880 Medical, LLC	WOLF Thrombectomy Device (K182835) (Primary)

Reference Device

Edwards LifeSciences	Fogarty Venous Thrombectomy Catheter (510K number unknown)

Description

The WOLF Thrombectomy V System is comprised of two single lumen composite, variable stiffness catheters. Both devices have a distal radiopaque marker for recognition under fluoroscopy. The WOLF Outer device has a collapsible braided funnel formed at its distal end. The purpose of the funnel is to enable more efficient ingestion of clot in larger vessels.

The system includes a preloaded weave and additional reloadable weaves. The weave and reloadable weave are fabricated from fine nitinol wire formed into a desirable tubular shape and attached to the WOLF Inner Catheter. The end of both weaves that are not attached to the WOLF Inner Catheter are cuffed with a radiopaque polymer. The WOLF outer catheter has hydrophilic coating to facilitate tracking and reduce friction during ingestion of the clot.

The WOLF inner catheter has one radiopaque marker band at the distal marker to indicate the tip of the catheter during tracking. The outer catheter has two sets of radiopaque markers. The distal most marker bands reside in the distal end of the funnel to facilitate visualization of the funnel. The second marker band is located at the base of the funnel to aid in positioning the funnel relative to the sheath during clot ingestion.

The reloadable weaves can be used for additional clot removal. A WOLF Thrombectomy V System used with a reloadable weave has the same principle of operation and mechanism of action as the system packaged with the preloaded weave.

Indication for Use

The WOLF Thrombectomy V System is indicated for the nonsurgical removal of emboli and thrombi from arterial and venous blood vessels in the peripheral vasculature.

Substantial Equivalence

The data presented in this submission demonstrates the technological similarity and equivalency of the WOLF Thrombectomy V System compared with the primary predicate device, the WOLF Thrombectomy Device. The devices have the same intended use (peripheral vascular), use the same mechanism of action, incorporate similar components, use similar construction and materials, are compatible with a guide sheath and are packaged and sterilized using the same processes. The 10F size is considered a line extension to offer the physician an additional option for treatment of larger peripheral blood vessels.

The review and analysis of the data demonstrate that the WOLF Thrombectomy V System, 10F is similar in intended use, benefits, risks, safety, and performance to the WOLF Thrombectomy Device, 6F and the reference device in the 10F size. Based on the design similarities between the 6F and 10F WOLF thrombectomy devices and the test results in the acute and chronic animal study using arterial and venous vessels, the devices are substantially equivalent. Biocompatibility, performance testing, simulated use testing, and animal testing demonstrate that the device has appropriate properties for its intended use. No new questions of safety are raised for the WOLF Thrombectomy V System.

Performance Data

Bench studies indicate that the DeVoro Medical WOLF Thrombectomy V System performs as intended. The following testing was performed in conformance with design inputs, including performance standards for peripheral vascular embolectomy devices. Testing included dimensional and functional design verification/validation (durability and integrity, kink radius, torsion and tensile strength, air and liquid leak testing, clot retrievability, resheathability, surface condition, coating integrity, particulate testing, corrosion resistance), sterilization validation, transit and package integrity testing, shelf life testing, acute and chronic animal safety testing, biocompatibility testing, simulated use testing, and comparative performance analysis with the predicate device. In addition, comparative testing of the Fogarty Venous Thrombectomy Catheter was conducted in the acute and chronic animal study in, both, arteries and veins.

Technical Comparison

The technical features of the WOLF Thrombectomy V System and the WOLF Thrombectomy Device are the same or similar for both the design components and the mechanism of action. Both devices are also provided sterile and are sterilized by the same method (EO). Both devices are made of similar materials and come in similar configurations (shape, diameter and lengths). The WOLF 10F is offered in additional configurations (funnel diameters and lengths). The Weave/Clot Grabber component in both devices is a tubular weave structure formed from nitinol wire and is attached to the distal end of the Inner Catheter. The Weave/Clot Grabber is the component that integrates and aids in ingesting the clot. The WOLF 10F package offers reloadable weaves attached to inner catheters. The reloadable weaves retain the same construction and are made of the same materials as the preloaded weave. Therefore, the reloadable weaves have the same construction and function to the preloaded weaves. Also, for both Inner and Outer Catheters are coaxial single lumen metallic/polymeric composites. The WOLF Thrombectomy V System does not require an aspiration source to engage the clot. Both the WOLF Thrombectomy V System and the WOLF device are delivered through the femoral artery or vein or other targeted vessel, provide delivery of contrast, and contain radiopaque markers for visualization under fluoroscopy. Both devices are used with introducer sheaths and guidewires and the WOLF Thrombectomy V System has been tested for compatibility with the appropriate accessories in preclinical (animal) testing and simulated use design validation testing.

Biocompatibility Testing

The WOLF Thrombectomy V System was subjected to the following biocompatibility testing per the ISO-10993-1 standard: cytotoxicity, sensitization, irritation/intracutaneous reactivity, acute systemic toxicity, material mediated pyrogenicity, hemolysis, complement activation and thromboresistance. The results showed that the WOLF Thrombectomy V System meets biocompatibility requirements of the ISO standard.

Sterilization Validation

Sterilization validation testing verified with a high degree of assurance that Ethylene Oxide sterilization is effective in achieving sterility of the WOLF Thrombectomy V System at a sterility assurance level of 10^{-6}.

Package Integrity After Aging and Distribution

Packaging was verified to protect the WOLF Thrombectomy V System adequately to ensure product function throughout the claimed shelf life and after exposure to the storage and distribution environment.

Animal Testing

The WOLF Thrombectomy V System was subjected to acute and chronic animal study to compare the safety of the WOLF device to a control device. The study was conducted per the US Food and Drug Administration, 21 CFR, Part 58 Good Laboratory Practice for Nonclinical Laboratory Studies. The purpose of this study was to assess the following safety endpoints:

1. The angiographic assessment of the vessel (presence or absence of dissection or perforation) due to use of the test article in the treated vessels.

2. The histopathological assessment of the vessel (degree of trauma and healing) due to use of the test article compared to vessels treated with the control.

The device passed all acceptance criteria outlined in the study protocol and should be deemed acceptable for clinical use.

Conclusions

The WOLF Thrombectomy V System and its predicate device have the same intended use and similar technological characteristics. The differences do not raise new questions of safety or effectiveness. Performance testing further demonstrates that the device is substantially equivalent to the predicate for its intended use.