October 19, 2021

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

Re: K210911
Trade/Device Name: WOLF Thrombectomy System, 14F
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: QEW
Dated: September 20, 2021
Received: September 21, 2021

Dear Roberta 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210911

Device Name
WOLF Thrombectomy System, 14F

Indications for Use *(Describe)*

The WOLF Thrombectomy System, 14F is indicated for:

- The nonsurgical removal of emboli and thrombi from arterial and venous blood vessels in the peripheral vasculature.
- Injection, infusion, and/or aspiration of contrast media and other fluids into or from a blood vessel.

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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TRADITIONAL 510(k) SUMMARY

DeVoro Medical, Inc WOLF Thrombectomy® System, 14F

General Company Information

Name:	DeVoro Medical, Inc.
Address:	46724 Lakeview Blvd Fremont, CA 94538
Contact:	Roberta Hines, Regulatory Consultant
Telephone:	425-766-0308
Email:	rhines@nwcrg.com

Date Prepared:	October 17, 2021

General Device Information

Product Name:	WOLF Thrombectomy® System, 14F
Common Name:	Embolectomy Catheter
Classification	Catheter, Embolectomy (21 CFR 870.5150, Product Code: QEW)
Primary Predicate Device	DeVoro Medical, Inc. WOLF Thrombectomy V System (10F) (K200101)
Reference Device	Inari Medical FlowTriever Retrieval/Aspiration System (K191710)

Description

The WOLF Thrombectomy System, 14F is comprised of two single lumen variable stiffness catheters (WOLF catheter & Devortex shaft) designed for use in removing clot from peripheral vessels. A funnel is attached to the distal end of the WOLF catheter to aid in ingestion of clot. The Devortex sleeve is attached to the Devortex shaft. When the Devortex shaft is pulled, it ingests the clot into the WOLF catheter. The WOLF catheter has hydrophilic coating to facilitate tracking and reduce friction during ingestion of the clot.

The Devortex shaft has one radiopaque marker band at the distal marker to indicate the tip of the catheter during tracking. The WOLF catheter has one radiopaque marker band at the base of the funnel to aid in positioning the funnel relative to the sheath during clot ingestion.

The WOLF Thrombectomy Sheath consists of a sheath, dilator and syringe. An active hemostatic valve is integrated at the proximal end of the sheath which can be manually opened for device introduction to provide hemostasis and minimize blood loss. The distal end of the sheath features a radiopaque marker forrecognition under fluoroscopy. The hemostasis valve is coupled with a large bore side port and is accompanied with a VacLok syringe for aspiration.

Indication for Use

The WOLF Thrombectomy System, 14F is indicated for:

- The nonsurgical removal of emboli and thrombi from arterial and venous blood vessels in the peripheral vasculature.
- Injection, infusion, and/or aspiration of contrast media and other fluids into or from a blood vessel.

Substantial Equivalence

The data presented in this submission demonstrates the technological similarity and substantial equivalence of the WOLF Thrombectomy System, 14F compared to the primary predicate device, the WOLF Thrombectomy V System 10F. The devices have the same overall intended use (embolectomy catheter used to remove thromboemboli from the peripheral vascular), use the same mechanism of action, incorporate similar components, incorporate reloads, use similar materials of construction, are compatible with a guide sheath and are packaged and sterilized using the same processes.

The WOLF Thrombectomy System, 14F also provides for the injection, infusion and aspiration of contrast media and other fluids into or from a blood vessel in a similar manner as the identified reference device, the Inari Medical FlowTriever Retrieval/Aspiration System, cleared under K191710. The WOLF Thrombectomy System, 14F has an expanded Indication for Use to include a WOLF Thrombectomy Sheath similar to the Triever Catheter of the FlowTriever System. Both devices are indicated for the nonsurgical removal of emboli and thrombi from arterial and venous blood vessels in the peripheral vasculature and for injection, infusion, and/or aspiration of contrast media and other fluids into or from a blood vessel.

The review and analysis of the data demonstrate that the WOLF Thrombectomy System, 14F is similar in overall intended use, indication for use, benefits, risks, safety, and performance as the WOLF Thrombectomy V System, 10F and the reference device's aspiration sheath. Based on the design similarities between the 14F subject device and the predicate 10F WOLF Thrombectomy V System, the devices are considered 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 System, 14F for its indication for use with an aspiration sheath.

Performance Data

Bench studies indicate that the DeVoro Medical WOLF Thrombectomy System, 14F performs as intended. The following testing was repeated 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 resistance, torsion and tensile strength, air and liquid leak testing, catheter tip durability, simulated use validation, coating integrity, particulate testing, and corrosion resistance). Sterilization validation for the subject device was conducted through the Product Adoption method. Transit and package integrity testing and shelf life testing were also repeated on the subject device and its packaging. Supporting data from the chronic

animal study for the predicate device apply to the subject device based on substantial equivalence between the devices; therefore, repeat testing was not required.

Technical Comparison

The technical features of the WOLF Thrombectomy System, 14F and the predicate device are the same or similar for both the design components and the mechanism of action. Both devices are provided sterile and are sterilized by the same method (EO). Both devices are made of similar materials, have the same reloads and are available in similar lengths. The French size of the subject WOLF device is larger. The Devortex sleeve component is the same as the predicate component which was previously referred to as the tubular weave structure formed from nitinol wire and is attached to the distal end of the Devortex shaft. The Devortex sleeve is the component that integrates and aids in ingesting the clot. Also, the WOLF catheter and Devortex shaft are coaxial single lumen metallic/polymeric composites. The WOLF Thrombectomy System, 14F has an aspiration sheath as a source to engage clot and is for exclusive use with the device. This design feature is similar to the Triever Catheter of the FlowTriever Retrieval/AspirationSystem reference device.

The subject device and its predicate are delivered through the femoral artery or vein or other targeted vessel, provide delivery of contrast and contain radiopaque markers for visualization under fluoroscopy. Each device is used with an introducer sheath and guidewire and the WOLF Thrombectomy System, 14F has been tested for compatibility with the appropriate accessories in simulated use design validation testing. Based on the similarities between the subject device and the predicate, preclinical (animal) testing conducted on the predicate device supports the safety and performance of the subject device. Design verification and validation was conducted for the aspiration sheath accessory.

Biocompatibility Testing

Biocompatibility testing was successfully performed in accordance with ISO 10993-1:2018 of another size in the WOLF family of devices. The data is applicable to the 14F WOLF Thrombectomy® System, 14F as both devices are comprised of the same materials. The biocompatibility tests performed were conducted in compliance with US Good Laboratory Practice (GLP) regulations of 21 CFR Part 58. All devices passed thereby verifying the biocompatibility of the WOLF Thrombectomy® System, 14F for its intended use.

Biocompatibility testing included:

- Cytotoxicity (ISO 10993-5)
- Sensitization (ISO 10993-10)
- Irritation or Intracutaneous Reactivity (ISO 10993-10)
- Material Mediated Pyrogenicity
- Acute Systemic toxicity (ISO 10993-11)
- Direct and indirect hemolysis (ISO 10993-4)
- Complement activation assay (ISO 10993-4)
- Hemocompatibility (ISO 10993-4)
- Partial thromboplastin time (ISO 10993-4)
- Extraction and Metals Screen
- Chemical Characterization (Sheath)
- Toxicological Assessment (Sheath)

Biocompatibility testing was also repeated for the WOLF Thrombectomy Sheath per ISO 10993-1 and demonstrated that the sheath is biocompatible for human use.

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 System, 14F and its aspiration sheath accessory at a sterility assurance level of 10^{-6}.

Package Integrity After Aging and Distribution

Packaging was verified to protect the WOLF Thrombectomy System, 14F and its sheath accessory adequately to ensure product function throughout the claimed shelf life and after exposure to the storage and distribution environment.

Animal Testing

Previous pre-clinical testing supports the safety and performance of the WOLF Thrombectomy System, 14F. Pre-clinical testing was not repeated for the System. An acute study in the ovine model was conducted to demonstrate radiopacity of the sheath.

Conclusions

The WOLF Thrombectomy System, 14F and its predicate device have the same overall intended use and similar technological and biological characteristics. The subject device has the same Indication for Use as the reference FlowTriever device for use with an aspiration sheath. The differences between the devices and its expanded Indication for Use do not raise new questions of safety or effectiveness.