August 27, 2021

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

Re: K210530
Trade/Device Name: WOLF Thrombectomy® System, 6F
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: QEW
Dated: August 23, 2021
Received: August 24, 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)*

K210530

Device Name

WOLF Thrombectomy System, 6F

Indications for Use *(Describe)*

The WOLF Thrombectomy System, 6F is indicated for the nonsurgical removal of emboli and thrombi from arterial and venous blood vessels in the peripheral vasculature.

The device is intended for single use only.

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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K210530

TRADITIONAL 510(k) SUMMARY

DeVoro Medical, Inc. WOLF Thrombectomy® System, 6F

Submitter

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

Date Prepared:	August 26, 2021
Trade Name of Device:	WOLF Thrombectomy® System, 6F
Common or Usual Name:	Embolectomy Catheter
Classification Name:	Catheter, Embolectomy
Regulation Number:	21 CFR 870.5150
Product Code:	QEW
Primary Predicate Device	880 Medical, LLC WOLF Thrombectomy Device (K182835) (now owned by DeVoro Medical, Inc.)
Secondary Predicate Device	DeVoro Medical, Inc. WOLF Thrombectomy V System (K200101)

Device Description

The WOLF Thrombectomy® System, 6F is comprised of two single lumen variable stiffness catheters (WOLF catheter & Devortex shaft) designed for use in removing clot from peripheral vasculature. The Devortex shaft is attached to the Devortex sleeve which when pulled, ingests the clot into the WOLF catheter. The WOLF Thrombectomy System, 6F is delivered through an access sheath that has an inner diameter of at least 0.087". Both the WOLF catheter and Devortex shaft have hydrophilic coating to facilitate tracking and reduce friction during ingestion of the clot. The Devortex shaft has one radiopaque marker band to indicate the tip of the catheter during tracking. The WOLF catheter has a distal radiopaque marker band toindicate its distal tip during tracking and pulling. The Devortex sleeve also has a radiopaque polymer cuff that allows for visualization of the weave movement during use.

Indication for Use

The WOLF Thrombectomy System®, 6F is indicated for the nonsurgical removal of emboli and thrombi from arterial and venous blood vessels in the peripheral vasculature.

Summary of Technological Characteristics

Comparative Evaluation of the DeVoro Medical WOLF Thrombectomy System, 6F to the Primary and Secondary Predicate Devices

Manufacturer / Device	Device Subject of Traditional 510(k)	Primary Predicate	Secondary Predicate
Device and Manufacturer	**WOLF Thrombectomy® System, 6F DeVoro Medical, Inc.**	**WOLF Thrombectomy Device (6F)880 Medical, Inc. (Now owned by DeVoro Medical, Inc.)**	**WOLF Thrombectomy V System (10F) DeVoro Medical, Inc.**
510(k) Number and Description	K210530	K182835	K200101
Regulation	21 CFR 870.5150	21 CFR 870.5150	21 CFR 870.5150
Regulation Description	An embolectomy catheter is a balloon-tippedcatheter that is used to remove thromboemboli, i.e., blood clots which have migrated in blood vessels from one site in the vascular tree to another.	An embolectomy catheter is a balloon-tipped catheter that is used to remove thromboemboli, i.e., blood clots which have migrated in blood vessels from one site in the vascular tree to another.	An embolectomy catheter is a balloon-tipped catheter that is used to remove thromboemboli, i.e., blood clots which have migrated in blood vessels from one site in the vascular tree to another.
Product Code	QEW	QEW	QEW
FDA Classification	Class II	Class II	Class II
Common Name	Embolectomy Catheter	Embolectomy Catheter	Embolectomy Catheter
Classification Name	Peripheral Mechanical Thrombectomy With Aspiration	Peripheral Mechanical Thrombectomy With Aspiration	Peripheral Mechanical Thrombectomy With Aspiration
Intended Use	To remove thromboemboli from the peripheral vasculature.	To remove thromboemboli from the peripheral vasculature.	To remove thromboemboli from the peripheral vasculature.
Indication for Use	The WOLF Thrombectomy Device is indicated for the nonsurgical removal of emboli and thrombi from arterial and venous blood vessels in the peripheral vasculature.	The WOLF Thrombectomy Device is indicated for the nonsurgical removal of emboli and thrombi from arterial blood vessels in the peripheral vasculature.	The WOLF Thrombectomy Device is indicated for the nonsurgical removal of emboli and thrombi from arterial and venous blood vesselsin the peripheral vasculature.
Design Features and Design Intent	The WOLF Thrombectomy System, 6F consists of a WOLF Catheter with a pre-loaded Devortex shaft which has a nitinol Devortex sleeve attached to the distal end of the Devortex shaft, two (2) Devortex shaft reloads with removable hubs, two (2) grabbing tools and a guidewire loading tool. The WOLF Catheter and Devortex shaft are both single lumen composite catheters which are intended to be loaded coaxially with each other. The Devortex sleeve is fabricated from fine, nitinol wire formed into a desirable shape and attached to the Devortex shaft.	The WOLF Thrombectomy Device is comprised of two coaxial single lumen catheters (WOLF Inner & Outer) designed foruse in removing clot from peripheral vascularvessels. The WOLF Device is delivered with athird coaxial catheter, a Guide Catheter or Sheath. The Inner catheter is attached to the nitinol weave structure which when pulled, ingests the clot into the Outer catheter which is pulled into the Guide Catheter upon its removal.	The WOLF Thrombectomy Device is comprised of two coaxial single lumen catheters (WOLF Inner & Outer) designed for use in removing clot from peripheral vascular vessels. The WOLFDevice is delivered with a third coaxial catheter,a Sheath. The Inner catheter is attached to the nitinol weave structure which when pulled, ingests the clot into the Outer catheter which is pulled into the sheath upon its removal. The Outer catheter has a braided funnel attached to its distal end. The funnel assists the weave in removing larger volumes of clot, seen in larger blood vessels (>4mm diam). Three

	If further clot ingestion is required, the Devortex shaft is fully removed from the WOLF Catheter and additional Devortex shafts (Reloads) are reloaded into the distalend of the WOLF Catheter by the user, as needed. A Devortex Reload Kit is packaged separately. The Kit includes three (3) WOLF Devortex Reloads placed into a packaging hoop on a hoop card. The additional Reloads enable further clot ingestion if desired.		size funnel devices are offered; 4mm, 6mm and 8mm OD funnels.
Technological Characteristics	Visualization: Radiopaque marker bands on fluoroscopy	Visualization: Radiopaque marker bands on fluoroscopy	Visualization: Radiopaque marker bands on fluoroscopy
	Effective Length: 110cm, 140cm Devortex Reload Kit: 140cm	Effective Length: 152cm	Effective Length: 110cm, 130cm
	Catheter Outer Diameter: 6F	Catheter Outer Diameter: 6F	Catheter Outer Diameter: 10F
	Vessel Compatibility: vessels larger 1.8mm	Vessel Compatibility: vessels larger 1.8mm	Vessel Compatibility: vessels that are larger than the funnel OD for the specific device (4, 6 or 8mm)
	Materials: Devortex sleeve: nitinol wire structure with urethane tungsten polymer and on its end. No hydrophilic coating on sleeve. Devortex shaft: stainless steel, Technora, Pebax polymers, colorant, Tungsten polymer,TPU Ink hydrophilic coating, polytetrafluoroethylene (PTFE), UV adhesive / cyanoacrylate. WOLF Catheter: stainless steel, Pebax polymers, nylon polymer, hydrophilic coating, TPU Ink, PTFE, platinum iridium. Three added colorants: white (titanium dioxide), yellow (iron oxide) & black (iron oxide). Hub Materials: Polycarbonate, silicone, UV adhesive / Cyanoacrylate, Cyanoacrylate, polyolefin Peelaway Sheath: PTFE, Cyanoacrylate	Materials: Weave: nitinol wire structure with urethane tungsten polymer and on its end & hydrophilic coating on weave. Inner Catheter: stainless steel, platinum iridium, Technora, UV epoxy, Pebax polymers, colorant, urethane polymers, Vestamid polymer, hydrophilic coating, polytetrafluoroethylene (PTFE), UV adhesive & cyanoacrylate. Outer Catheter: nitinol, stainless steel, Pebaxpolymers, urethane polymers, nylon polymer, colorant, hydrophilic coating, PTFE, platinum iridium, solder flux. Hub Materials: Stainless steel, TPU Ink solder, flux, UV epoxy, silicone polycarbonate, cyanoacrylate Peelaway Sheath: PTFE	Materials: Weave: nitinol wire structure & a urethane polymer on its end. No hydrophilic coating on weave. Inner Catheter: stainless steel, platinum iridium, HDPE, LDPE and Pebax polymers, polytetrafluoroethylene (PTFE), UV adhesive / cyanoacrylate. Outer Catheter: stainless steel, Pebax polymers, nylon polymer, hydrophilic coating, PTFE, platinum iridium. Hub Materials: Polycarbonate, silicone, UV adhesive / cyanoacrylate. Peelaway Sheath: PTFE, poly-lactic acid, UV adhesive / cyanoacrylate.
	Performance: equivalent to predicate devices	Performance: meets product specifications for its intended use	Performance: meets product specifications for its intended use

	Guidewire compatibility: 0.014"	Guidewire compatibility: 014"	Guidewire compatibility: 0.035"
	Sterilization Method: EO and nonpyrogenic	Sterilization Method: EO and nonpyrogenic	Sterilization Method: EO and nonpyrogenic

The technical features of the WOLF Thrombectomy® System, 6F and the primary predicate device, the WOLF Thrombectomy Device (6F), are the same or similar including design components and the mechanism of action. Both devices have the same materials and come in multiple sleeves (weaves) and usable lengths, are guidewire and sheath compatible, are compatible with saline and contrast, are provided sterile and have the same sterilization method. Both devices are radiopaque, have similar packaging, and are biocompatible for human use. Several studies conducted on the primary and secondary predicate devices apply to the subject device based on the similarities between them, including stability over time, pre-clinical safety and performance, compatibility with saline and contrast and some functional and simulated use testing. Both the WOLF subject device and both predicate devices are delivered through the femoral artery and contain radiopaque markers for visualization under fluoroscopy. The subject device reloads within the package are the same as the secondary predicate device. Funnels, which are a design feature of the secondary predicate, are intended to treat larger vessels 4mm and larger. Since the 6F device is intended to treat 1.8mm or larger vessels, funnels are not required.

Performance Data

Bench studies indicate that the DeVoro Medical WOLF Thrombectomy® System, 6F 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, shelf life testing were also repeated on the subject device and its packaging. Supporting data from the acute and chronic animal study for the secondary predicate device apply to the subject device basedon substantial equivalence between the devices; therefore, this repeat testing was not required.

Biocompatibility Testing

Biocompatibility for the WOLF Thrombectomy® System, 6F was repeated due to the addition of three colorants (white (titanium dioxide), yellow (iron oxide) & black (iron oxide), and one new manufacturing process change replacing a soldering joint process with a laser welding process. The following tests were conducted per the ISO-10993-1 standard including:

- Cytotoxicity – MEM Elution
- Sensitization - Guinea Pig Maximization Test, 2 extracts
- Irritation or Intracutaneous Reactivity
- Material Mediated Pyrogenicity
- Acute Systemic toxicity
- Direct and indirect hemolysis
- Complement activation assay
- Heparinized Platelet and Leukocyte Count Assay, with comparison Article

- Partial thromboplastin time
- Thrombogenicity – In Vitro Blood Loop test

In addition to the biocompatibility tests listed above, testing for extractables and leachables was conducted on the WOLF Thrombectomy System, 6F.

The tests concluded that there are no chemical, toxicological, or safety risks from the WOLF Thrombectomy® System, 6F components, manufacturing procedures and sterilization process and the device is considered biocompatible for its intended use as ISO 10993-1 category: externally communicating device, limited < 24 hour contact with circulating blood exposure.

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, 6F at a sterility assurance level of 10^{-6}.

Package Integrity After Aging and Distribution
Packaging was verified to protect the WOLF Thrombectomy® System, 6F adequately to ensure product function throughout the claimed shelf life and after exposure to the storage and distribution environment.

Animal Testing
Previous pre-clinical studies for the device's primary and secondary predicates support the safety and performance of the WOLF Thrombectomy® System, 6F. Pre-clinical testing was not repeated for the subject device.

Conclusions
Based on a comparison of the intended use/indications for use, technological characteristics, and the results from a series of non-clinical tests, the WOLF Thrombectomy® System, 6F has demonstrated substantial equivalence to the predicate device. The differences between the devices and its expanded Indication for Use do not raise new questions of safety or effectiveness.