November 10, 2022

DeVoro Medical, Inc
Vanessa Fowler
Principal Regulatory Affairs Specialist
One Scimed Place
Maple Grove, MN 55311

Re: K221391
Trade/Device Name: WOLF Thrombectomy SmartClaw Catheter
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: QEW, KRA
Dated: October 6, 2022
Received: October 6, 2022

Dear Vanessa Fowler:

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,

for Sara M. Royce -S
Digitally signed by Sara M. Royce -S
Date: 2022.11.10 14:55:45 -05'00'

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)*
K221391

Device Name
WOLF Thrombectomy SmartClaw Catheter

Indications for Use *(Describe)*
The WOLF Thrombectomy SmartClaw Catheter, in conjunction with the WOLF Thrombectomy Aspiration Sheath, 14F, is indicated for:
• the non-surgical removal of thrombi and emboli 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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510(k) Summary for K221391
Per 21 CFR §807.92

Sponsor	DeVoro Medical, Inc 46724 Lakeview Blvd. Fremont, CA 94538 USA
Contact Name and Information	Vanessa Fowler Principal Regulatory Affairs Specialist One Scimed Place Maple Grove, MN 55311-1566 Phone: 763-494-2537 Fax: 763-494-2222 e-mail: Vanessa.Fowler@bsci.com
Date Prepared	October 6, 2022
Proprietary Name	WOLF Thrombectomy™ SmartClaw Catheter
Common Name	Catheter, Embolectomy Peripheral Mechanical Thrombectomy with Aspiration
Primary Product Code	QEW
Subsequent Product Code	KRA
Classification	Class II, 21 CFR Part 870.5150
Predicate Device	WOLF Thrombectomy System, 14F (K210911), cleared October 19, 2021
Reference Device	Fogarty Venous Thrombectomy Catheter, 510(k) unknown
Device Description	The WOLF Thrombectomy SmartClaw Catheter is a thrombectomy catheter designed to work solely with the currently marketed WOLF Thrombectomy Sheath (K210911). The device consists of an inner catheter shaft, outer catheter shaft, heat set nitinol braid, and an actuation handle assembly connected to the proximal ends of the shafts. There are two device configurations that only differ in length of the expandable nitinol braided basket. The two configurations are identified by the max diameter of the expanded basket (20mm, 32mm). The WOLF Thrombectomy SmartClaw Catheter is introduced through the WOLF Sheath and delivered to the targeted vessel location under fluoroscopy and standard endovascular techniques using a commercially available guidewire. The distal nitinol basket is expanded by moving the handle slider proximally and the clot may then be pulled proximally towards and aspirated through the WOLF Sheath.
Intended Use of Device	Removal of thromboemboli from the peripheral vasculature.
Indications for Use	The WOLF Thrombectomy SmartClaw Catheter, in conjunction with the WOLF Thrombectomy Aspiration Sheath, 14F, is indicated for: • the non-surgical removal of thrombi and emboli 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.

Comparison of Device Characteristics	The WOLF Thrombectomy SmartClaw Catheter, as used with the WOLF Thrombectomy Aspiration Sheath 14F, incorporates substantially equivalent design, packaging, fundamental technology, and intended use as those featured in the predicate, the WOLF Thrombectomy System, 14F.See table below for additional detail.

Characteristics	**Predicate Device – WOLF Thrombectomy System 14F**	**Subject Device – WOLF Thrombectomy SmartClaw Catheter**
Intended Use	Removal of thromboemboli from the peripheral vasculature.	SAME
Indications for Use	The WOLF Thrombectomy System, 14F is indicated for: • the non-surgical removal of thrombi and emboli 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.	
Device Class	Class II per 21 CFR 870.5150	
Materials	Nitinol weave structure attached to polymer catheter.	Braided nitinol basket on polymer catheter.
Operating Principal	The inner catheter is attached to the nitinol weave structure which engages clot, and when pulled the weave ingests the clot into the outer catheter. Aspiration is applied via the WOLF Sheath.	Nitinol basket is expanded and pulled to remove thrombus. Aspiration is applied via the WOLF sheath.
Effective Length	WOLF Catheter: 110 and 130 cm configurations available. WOLF Sheath: 75 or 95 cm configurations available.	SmartClaw: 115 cm SmartClaw is compatible with the 75 cm WOLF sheath.
How provided	Sterile, single use	SAME
Guidewire Compatibility	Compatible with 0.035" guidewire	SAME
Visualization	Radiopaque marker bands visible under fluoroscopy	Radiopaque marker band, basket visible under fluoroscopy

Performance Data	Bench, animal, and biocompatibility testing were performed to support a determination of substantial equivalence. The results of these tests provide reasonable assurance that the proposed device has been designed and tested to assure conformance to the requirements for its intended use. No new safety or performance issues were raised during the testing. The following biocompatibility tests were completed on the WOLF Thrombectomy SmartClaw Catheter: • Cytotoxicity • Sensitization • Intracutaneous Reactivity • Acute Systemic Toxicity • Materials Mediated Pyrogenicity • Extract and Direct Contact Hemolysis • Complement Activation • Partial Thromboplastin Time • In Vitro Hemocompatibility • Platelet and Leukocyte Counts The following *in-vitro* performance tests were completed for the WOLF Thrombectomy SmartClaw Catheter. • Simulated Use • Corrosion • Torsion • Trackability • Dimensional Verification • Mechanical Integrity • Kink Resistance • Packaging Validation Additionally, a GLP animal study was performed to evaluate equivalent safety of the WOLF Thrombectomy SmartClaw Catheter.
Conclusion	Based on the indications for use, technological characteristics, and safety and performance testing, the WOLF Thrombectomy SmartClaw Catheter has been shown to be appropriate for its intended use and is considered to be substantially equivalent to the WOLF Thrombectomy System, 14F (K210911).