May 29, 2024

DeVoro Medical, Inc.
Aaron Lynch
Regulatory Affairs Specialist II
10700 Bren Rd W
Minnetonka, Minnesota 55343

Re: K241207
Trade/Device Name: SmartClaw™ Thrombectomy Catheter, 20 mm (FD0660-01), SmartClaw™ Thrombectomy Catheter, 32 mm (FD0660-02)
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: QEW
Dated: April 30, 2024
Received: April 30, 2024

Dear Aaron Lynch:

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.

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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Gregory W. O'connell -S

Digitally signed by Gregory W. O'connell -S
Date: 2024.05.29 15:54:50 -04'00'

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K241207

Device Name
SmartClaw™ Thrombectomy Catheter, 20 mm (FD0660-01);
SmartClaw™ Thrombectomy Catheter, 32 mm (FD0660-02)

Indications for Use *(Describe)*
The SmartClaw Thrombectomy Catheter is indicated for the non-surgical removal of thrombi and emboli from 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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510(k) Summary for K241207
Per 21 CFR §807.92

Sponsor	DeVoro Medical, Inc. 10700 Bren Rd W Minnetonka, MN 55343-9679
Contact Name and Information	Aaron Lynch Regulatory Affairs Specialist II One Scimed Place Maple Grove, MN 55311-1566 Phone: (508) 521-4235 Email: aaron.lynch@bsci.com
Date Prepared	May 24, 2024
Proprietary Name	SmartClaw™ Thrombectomy Catheter, 20 mm (FD0660-01), SmartClaw™ Thrombectomy Catheter, 32 mm (FD0660-02)
Common Name	Catheter, Embolectomy Peripheral Mechanical Thrombectomy with Aspiration
Primary Product Code	QEW
Classification	Class II, 21 CFR Part 870.5150
Predicate Device	WOLF Thrombectomy™ SmartClaw Catheter (K221391), cleared on November 10, 2022
Device Description	The SmartClaw™ Thrombectomy Catheter is a mechanical thrombectomy catheter designed to work with commercially available sheaths sized 8F or larger. The device consists of an inner catheter shaft, outer catheter shaft, heat set nitinol braid, and an actuation handle attached to the proximal ends of the shafts. There are two device configurations that differ only in length of the expandable nitinol braided basket. The two configurations are identified by the maximum diameter of the expanded basket (20 mm, 32 mm). The SmartClaw™ Thrombectomy Catheter is introduced through a commercially available sheath sized 8F or larger and delivered to the targeted vessel location under fluoroscopy and standard endovascular techniques using a commercially available guidewire. After it is delivered to the targeted vessel location, the catheter's distal nitinol basket is expanded by moving the handle slider proximally. Fluoroscopic guidance is used to ensure the expanded basket achieves a 1:1 ratio with the vessel diameter. Subsequently, the SmartClaw™ Thrombectomy Catheter is retracted proximally to pull loosened clot towards the sheath. Then, the clot is removed from the patient via aspiration or another commercially available clot removal method as appropriate for procedure requirements. After the clot is removed, the catheter's distal nitinol basket is collapsed, and the SmartClaw™ Thrombectomy Catheter is withdrawn from the targeted vessel location through the sheath.
Intended Use of Device	Removal of thromboemboli from the peripheral vasculature
Indications for Use	The SmartClaw™ Thrombectomy Catheter is indicated for the non-surgical removal of thrombi and emboli from the peripheral vasculature.

Device Technology Characteristics and Comparison to Predicate Device	The SmartClaw™ Thrombectomy Catheter incorporates substantially equivalent design, packaging, fundamental technology, and intended use as those featured in the predicate, the WOLF Thrombectomy™ SmartClaw Catheter (K221391). The subject device's indications for use are being modified to remove reference to the WOLF Thrombectomy Aspiration Sheath, 14F (K210911), thereby allowing the SmartClaw™ Thrombectomy Catheter to be used with commercially available sheaths sized 8F or larger.

Characteristic	Subject Device SmartClaw™ Thrombectomy Catheter	Predicate Device WOLF Thrombectomy™ SmartClaw Catheter (K221391)
Intended Use	Removal of thromboemboli from the peripheral vasculature	Identical
Indications for Use	The SmartClaw™ Thrombectomy Catheter is indicated for the non-surgical removal of thrombi and emboli from the peripheral vasculature.	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.
Device Class	Class II per 21 CFR 870.5150	Identical
Catheter Design	Outer catheter shaft, inner catheter shaft, heat set nitinol braid, and actuation handle	Identical
Effective Length	145 cm	115 cm
How provided	Sterile, single use	Identical
Sheath Compatibility	Commercially available sheaths sized 8F or larger	WOLF Thrombectomy Aspiration Sheath, 14F (K210911)
Guidewire Compatibility	Compatible with 0.035 in (0.89 mm) guidewire	Identical

Characteristic	Subject Device SmartClaw™ Thrombectomy Catheter	Predicate Device WOLF Thrombectomy™ SmartClaw Catheter (K221391)
Operating Principle/ Mechanism of Action	The SmartClaw™ Thrombectomy Catheter is delivered through a commercially available sheath of appropriate size (≥ 8F) into or beyond the clot. The SmartClaw™ Thrombectomy Catheter is expanded to the vessel diameter via actuation of the handle slider. The SmartClaw™ Thrombectomy Catheter is retracted proximally to pull loosened clot towards the sheath. Then, the clot is removed from the patient via aspiration or another commercially available clot removal method as appropriate for procedure requirements.	The WOLF Thrombectomy™ SmartClaw Catheter is delivered through the WOLF Sheath past the clot location. The WOLF Thrombectomy™ SmartClaw Catheter is expanded to the vessel diameter via actuation of the handle slider. The WOLF Thrombectomy™ SmartClaw Catheter is pulled moving the thrombus towards the WOLF Sheath. The clot is removed via the WOLF Sheath and/or the WOLF Thrombectomy System.
Visualization	Radiopaque marker band, basket visible under fluoroscopy	Identical

Non-clinical Performance Data	Determination of substantial equivalence is based on an assessment of non-clinical performance data. Non-clinical performance data includes bench-top performance evaluations and packaging validations. **Bench Testing:** Bench testing was performed to evaluate physical integrity, functionality and performance of the catheter. Performance criteria includes: visual inspection; dimension requirements; mechanical integrity; fluid leakage; kink resistance; torsion; and guidewire and sheath compatibility. **Packaging Validation:** The integrity of the packaging configuration was evaluated in accordance with ISO 11607-1 and ISO 11607-2. Testing was conducted on fully packaged units after ethylene oxide sterilization, climatic conditioning, and distribution challenge conditioning. The results of these tests demonstrate the subject 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.
Clinical Testing	Clinical studies are not required to demonstrate substantial equivalence of the SmartClaw Thrombectomy Catheter.
Conclusion	Based on the indications for use, technological characteristics, and performance testing, the SmartClaw Thrombectomy Catheter has been shown to be appropriate for its intended use and is considered substantially equivalent to the WOLF Thrombectomy SmartClaw Catheter (K221391).