



March 27, 2019

880 Medical, LLC  
% Ms. Roberta Hines  
Regulatory Consultant  
Northwest Clinical Research Group, Inc.  
19836 NE 125th Place  
Woodinville, WA 98077

Re: K182835

Trade/Device Name: WOLF Thrombectomy Device  
Regulation Number: 21 CFR 870.5150  
Regulation Name: Embolectomy Catheter  
Regulatory Class: Class II  
Product Code: DXE  
Dated: February 19, 2019  
Received: February 22, 2019

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm>); 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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). 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 (<http://www.fda.gov/DICE>) for more information or contact DICE by email ([DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

**Eleni  
Whatley** Digitally signed  
by Eleni Whatley  
Date: 2019.03.27  
13:17:55 -04'00'

For

Bram D. Zuckerman, M.D.  
Director  
Division of Cardiovascular Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K182835

Device Name

WOLF Thrombectomy Device

Indications for Use (Describe)

The WOLF Thrombectomy Device is indicated for the nonsurgical removal of emboli and thrombi from arterial 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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## 510(k) SUMMARY

### 880 Medical, LLC WOLF Thrombectomy Device

K182835

#### General Company Information

Name: 880 Medical, LLC  
Address: 46714 Fremont Blvd.  
Fremont, CA 94538, USA  
Contact: Roberta Hines, Regulatory Consultant  
Telephone: 425-766-0308  
Email: [rhines@nwcrq.com](mailto:rhines@nwcrq.com)

#### Date Prepared

February 19, 2019

#### General Device Information

Product Name: WOLF Thrombectomy Device  
Common Name: Thrombectomy Catheter  
Classification: Catheter, Embolectomy (21 CFR 870.5150, Product Code: DXE)

#### Predicate Devices

Inari Medical, Inc. Inari Medical Infusion Aspiration Catheter System, also known as the FlowTrievers (K143563) (Primary)

#### Reference Device

Penumbra, Inc. Penumbra Embolectomy Aspiration System (INDIGO Aspiration System) (K142870)

#### Description

The WOLF Thrombectomy Device is comprised of two single lumen variable stiffness catheters (WOLF Inner & Outer) designed for use in removing clot from arterial peripheral vessels. The WOLF inner catheter is attached to the weave which when pulled, ingests the clot into the WOLF outer catheter. The WOLF device is delivered through a guide catheter that has an inner diameter of at least 0.068". Both WOLF catheters have hydrophilic coating to facilitate tracking and reduce friction during ingestion of the clot.

The WOLF inner catheter has two radiopaque marker bands. The distal marker is used to indicate the tip of the catheter during tracking. The proximal marker is used to indicate how far the physician should pull back the GC prior to pulling. The outer catheter has a distal radiopaque marker band to indicate its distal tip during tracking and pulling. The weave also has a radiopaque polymer cuff that allows for visualization of the weave movement.

#### Indication for Use

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



### **Substantial Equivalence**

The data presented in this submission demonstrates the technological similarity and equivalency of the WOLF Thrombectomy Device compared with the primary predicate device, the Inari Medical Infusion Aspiration Catheter System.

The devices have the same intended use (peripheral vascular), use the same mechanism of action, incorporate similar components, use similar construction and material, are compatible with a guide catheter/sheath and are packaged and sterilized using the same processes.

Both devices are coaxial systems consisting of an Inner catheter with a metallic/polymer composite, an Outer catheter with a metallic/polymer composite, and a nitinol Weave/Clot Grabbing structure attached to the distal end of the Inner catheter.

In addition to the primary predicate device, a reference device has been included in this submission to support substantial equivalence to a marketed device. The INDIGO Aspiration Catheter and Separator is considered as a reference device because it has the same intended use, same mechanisms of actions and its 5F device is used in similar sized vessels as the WOLF Thrombectomy Device.

Biocompatibility, performance testing, simulated use testing, and animal testing demonstrate that the device has appropriate properties for its intended use.

### **Performance Data**

Bench studies indicate that the 880 Medical WOLF Thrombectomy Device 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, chronic animal safety testing, biocompatibility testing, simulated use testing, and comparative performance analysis with the predicate device. In addition, comparative testing of the INDIGO Aspiration Catheter was conducted in the simulated use test.

### **Technical Comparison**

The technical features of the WOLF Thrombectomy Device and the Inari FlowTrieve 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 the WOLF Thrombectomy and Inari FlowTrieve Device have the same four main design components, highlighting their similarities in design:

1. Weave/Clot Grabber – attached to distal end of Inner Catheter
2. Inner Catheter
3. Outer Catheter
4. Aspiration Source

Both devices are made of similar materials and come in similar configurations (shape, diameter 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 into the clot and aids in clot removal. Also, for both devices the Inner and Outer Catheters are coaxial single lumen metallic/polymeric composites with hydrophilic coating. The aspiration source for both the WOLF Thrombectomy Device and the Inari FlowTrieve is a syringe-based design.



Both the WOLF Thrombectomy Device and Inari FlowTrieve Device are delivered through the femoral artery, provide delivery of contrast, and contain radiopaque markers for visualization under fluoroscopy. Both devices are used with introducer sheaths/guide catheters and guidewires. The WOLF Thrombectomy Device has been tested for compatibility with the appropriate accessories in preclinical (animal) testing and simulated use design validation testing.

### **Biocompatibility Testing**

The WOLF Thrombectomy Device was subjected to the following biocompatibility testing per the ISO-10993-1 standard: cytotoxicity, sensitization, irritation/intracutaneous reactivity, acute systemic toxicity, pyrogenicity, hemocompatibility testing (partial thromboplastin time, assay for coagulation and hematology parameters, and hemolysis) and endotoxin testing. The results showed that the WOLF Thrombectomy Device 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 880 WOLF Thrombectomy Device at a sterility assurance level of  $10^{-6}$ .

### **Package Integrity After Aging and Distribution**

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

### **Animal Testing**

The WOLF Thrombectomy Device 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 angiographic damage to the target vessel on Day 0 and on Day 28 and histopathological assessment of damage to the target vessel on Day 0 and Day 28. The objectives, as well as the acceptance criteria for success, were met. No evidence of vessel dissection or perforation was seen acutely or through histopathology at the acute and chronic time points. When analyzed histologically, the treatment with the WOLF device resulted in equivalent or less endothelial erosion and mural injury as the control device. Acute injury was minimal and consistent with catheterization procedures. Vessel injuries were found to have healed completely and resulted in full re-endothelialization by the chronic time point (28 days).

### **Conclusions**

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