February 15, 2023

Endovascular Engineering
Debra Cogan
VP Regulatory & Clinical
3925 Bohannon Drive, Suite 300
Menlo Park, California 94025

Re: K223891
Trade/Device Name: Cobra Catheter System
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: QEW, KRA
Dated: December 22, 2022
Received: December 27, 2022

Dear Debra Cogan:

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 W. O'connell -S
Digitally signed by Gregory W. O'connell -S
Date: 2023.02.15 15:38:50 -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)*
K223891

Device Name
Cobra Catheter System

Indications for Use *(Describe)*
The Cobra Catheter System is indicated for:
• The non-surgical removal of thrombi and emboli from venous vasculature.
• Injection, infusion, and/or aspiration of contrast media and other fluids into or from the venous 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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TRADITIONAL 510(k) SUMMARY - K223891

Endovascular Engineering Cobra Catheter System

I. SUBMITTER

Name:	Endovascular Engineering
Address:	3925 Bohannon Drive, Suite 300 Menlo Park, CA 94025, USA
Contact:	Debra Cogan, VP Regulatory & Clinical
Telephone:	408-515-0820
Email:	dcogan@endovascularengineering.com
Date Prepared:	February 13, 2023

II. DEVICE

Name of Device:	Cobra Catheter System
Common or Usual Name:	Embolectomy Catheter
Classification Name:	Catheter, Embolectomy
Regulatory Class:	II
Regulation Number:	21 CFR 870.5150
Product Code:	QEW, KRA

III. PREDICATE DEVICE

Primary Predicate Device:	Inari Medical ClotTriever Thrombectomy System (K212632)
Reference Predicate Device:	Argon Medical Devices Cleaner Plus Thrombectomy System (K211798)

IV. DEVICE DESCRIPTION

The Cobra Catheter System (Cobra System) is a minimally invasive aspiration catheter with an integrated handle that connects to a commercially available vacuum pump. The aspiration catheter has an expanding funnel at the distal end for clot capture and features radiopaque markers for visibility under fluoroscopic guidance. The funnel resides within the outer sleeve of the aspiration catheter until it is manually deployed in the target vessel using the slider on the handle. The Cobra System can be initially introduced with a 16Fr introducer sheath. The Cobra System allows for navigating to, engagement, ingestion, and transportation of the target obstructive clot out of the peripheral veins to re-establish blood flow from the lower extremities.

The Cobra System is comprised of four (4) components:

- Aspiration Catheter: The Aspiration Catheter includes a catheter shaft with a funnel at the distal end and an integrated handle that allows for manual control of the device features. The handle features a port for the purposes of fluid injection, flushing of the inner lumen of the Aspiration Catheter and for measurement of intravascular pressure using a standard pressure line setup, if needed. The Aspiration Catheter is compatible with standard accessories such as a 0.035" or 0.038" guidewire.

- Agitator: The Agitator is intended to be inserted in the inner lumen of the Aspiration Catheter and connects to the proximal end of the handle. The Agitator is designed to mechanically disrupt emboli within the distal region of the Aspiration Catheter lumen during aspiration. The Agitator may be disconnected, removed, and reintroduced through the Aspiration Catheter System during use.

- Rotating Hemostasis Valve (RHV): The RHV is an accessory that attaches to the proximal end of the Aspiration Catheter when the Agitator is removed from the Aspiration Catheter. The RHV includes a Tuohy-Borst valve to enable compatibility with the Dilator as well as sealing on ancillary devices, such as guidewires or diagnostic catheters.

- Dilator: An optional accessory to the Cobra System. The Dilator is compatible with 0.035" or 0.038" guidewires and can be used to facilitate navigation.

V. INDICATIONS FOR USE

The Cobra Catheter System is indicated for:

- the non-surgical removal of emboli and thrombi from venous vasculature
- injection, infusion, and/or aspiration of contrast media and other fluids into or from venous vasculature.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES `

The technical features of the Cobra Catheter System and the primary and reference predicate devices are the same or similar for both the design components and the mechanism of action. All 3 devices are single-use, disposable, catheter-based technologies that are provided sterile and are sterilized by the same method (EtO). Like both predicate devices, the Cobra Catheter System is delivered over a dilator with a guidewire to the target clot. The working length of all 3 devices are clinically relevant for treating peripheral thrombosis. The subject device and the primary predicate both feature a self-expanding element for capturing clot**.** The subject device and reference predicate both feature an agitator for macerating clot and applying suction using a powered vacuum pump.

Characteristic	Subject Device	Primary Predicate	Reference Predicate
Device Name	Cobra Catheter System	ClotTriever Thrombectomy System	Cleaner Plus Thrombectomy System
Manufacturer	Endovascular Engineering, Inc.	Inari Medical, Inc.	Argon Medical Devices, Inc.
510(k) Number	K223891	K212632	K211798
Classification	II	II	II
Classification Name	Embolectomy Catheter	Embolectomy Catheter	Embolectomy Catheter
Regulation Number	870.5150	870.5150	870.5150
Product Code	QEW. KRA	QEW	QEW, KRA

Characteristic	Subject Device	Primary Predicate	Reference Predicate
Intended Use	Thrombus removal	Thrombus removal	Thrombus removal
Indications for Use	The Cobra Catheter System is indicated for: • The non-surgical removal of emboli and thrombi from venous vasculature. • Injection, infusion, and/or aspiration of contrast media and other fluids into or from venous vasculature.	The ClotTriever Thrombectomy System is indicated for: • The non-surgical removal of thrombi and emboli from blood vessels. • Injection, infusion, and/or aspiration of contrast media and other fluids into or from blood vessels. The ClotTriever Thrombectomy System is intended for use in the peripheral vasculature including deep vein thrombosis (DVT).	Indicated for mechanical de-clotting, aspiration, and controlled and selective infusion of physician-specified fluids, including thrombolytics, in the peripheral venous vasculature.
Target Anatomy	Peripheral vasculature	Peripheral vasculature	Peripheral vasculature
Guidewire access	OTW	OTW	OTW
Sheath inner diameter	16F	16F, 19F	10 & 12F
Catheter working length	95cm	80cm	65cm & 135 cm
IEC 60601 Compliance	Yes	N/A	Yes
Mechanism of action	Mechanical maceration and aspiration of thrombus using a vacuum pump for suction.	Cores, captures and removes thrombus with supplemental manual suction using a large bore syringe.	Mechanical maceration and aspiration of thrombus using a vacuum pump for suction.
Single Use	Yes	Yes	Yes
Sterile	Yes	Yes	Yes
Sterilization Method	EtO	EtO	EtO
Performance Tests	• Visual and Dimensional Inspection • Sheath Compatibility • Deployment/Retraction Force • Vacuum Compatibility • Pressure Connection • Trackability • Simulated Use • Accessibility • Durability • Suction Valve Force • Heat Generation • Guidewire Compatibility • Corrosion Resistance • Tensile Testing • Torque Testing • Pouch Seal Inspection • Pouch, Peel, Seal Strength • Particulate Matter • Biocompatibility Validation • Sterilization Validation • IEC 60601 Compliance	• Visual and Dimensional Inspection • ClotTriever Sheath Compatibility • Deployment/Retraction Force • Kink Radius • Fluid Leakage, Sheath • Vacuum Leakage, Sheath • Simulated Use, Track & Rotation • Simulated Use, Track & Tensile	• Wire – Atraumatic Tip Pull • Wire – Corrosion Resistance • Wire – Fatigue • Wire – Dynamic Retention • Wire – Flexing and Fracture • Wire – Kink • Wire – Tensile Break • Wire – Dimensional • Catheter – Dimensional • Catheter – Aspiration Tip Collapse • Catheter – Kink • Catheter – Hemostasis Valve Leak • Catheter – Torsional Break • Catheter – System Leak • Catheter – Tensile Break • Shipping Qualification • Luer Functional • Catheter – Coating Performance and Integrity • IEC 60601 Compliance • Canister & Dead Volume Study • Pump Functionality - Relief Valve • Pump Tubing – Pull • Pump Performance • Pump – Button Press Endurance • Simulated Use • Handpiece Dimensional

Characteristic	Subject Device	Primary Predicate	Reference Predicate
			• Handpiece Motor & Battery Performance • Pump Battery Performance • Handpiece – Functionality • Handpiece – Peel-away Introducer • Luer Dimensional • Radiopacity • Functional, Performance, and Software Testing • Float Valve Study

VII. PERFORMANCE DATA

Bench studies indicate that the Cobra Catheter System performs as intended. Testing was performed in conformance with design inputs, including performance standards for peripheral vascular embolectomy devices. Testing included:

- Visual and Dimensional Inspection
- Sheath Compatibility
- Deployment/Retraction Force
- Vacuum Compatibility
- Pressure Connection
- Trackability
- Simulated Use
- Accessibility
- Durability
- Suction Valve Force
- Heat Generation
- Guidewire Compatibility
- Corrosion Resistance
- Tensile Testing
- Torque Testing
- Pouch Seal Inspection
- Pouch, Peel, Seal Strength
- Particulate Matter

Sterilization Validation
Sterilization validation was conducted on the Cobra Catheter System and demonstrated a sterility assurance level of 10^{-6}.

Biocompatibility Testing
Biocompatibility testing was conducted per the requirements of ISO-10993-1, Biological Evaluation of Medical Devices.

The tests concluded that there is no chemical, toxicological, or safety risks from the Cobra Catheter System 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.

Electrical safety and electromagnetic compatibility (EMC)
Electrical safety and EMC testing was conducted on the Cobra Catheter System and complies with IEC 60601-1 and IEC 60601-2.

Animal Testing
The Cobra Catheter System was subjected to an animal study. The study was conducted per the US Food and Drug Administration, 21 CFR, Part 58 Good Laboratory Practice for Nonclinical Laboratory Studies. The Cobra Catheter System and control device showed similar results of performance evaluations, post-treatment and interim angiographies, animal health conditions, and pathologic responses.

VIII. CONCLUSIONS

The Cobra Catheter System and its predicate devices 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 devices for its intended use.