May 20, 2024

Edwards Lifesciences
Aeree Lee
Sr Manager, Regulatory Affairs
1 Edwards Way
Irvine, California 92614

Re: K233619
Trade/Device Name: Fogarty Corkscrew Catheters (140806, 140808, 1408010); Fogarty Graft Thrombectomy Catheters (160245F, 160246F)
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy catheter
Regulatory Class: Class II
Product Code: DXE
Dated: November 9, 2023
Received: November 13, 2023

Dear Aeree Lee:

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 and Part 809); 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: 2024.05.20 17:08:08 -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)*
K233619

Device Name
Fogarty Corkscrew Catheters (140806, 140808, 1408010)

Indications for Use *(Describe)*
The Fogarty Corkscrew Catheter is indicated for use in adult patients with emboli/thrombi in the peripheral arterial vasculature in either native vessels or synthetic grafts.

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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The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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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)*
K233619

Device Name
Fogarty Graft Thrombectomy Catheters (160245F and 160246F)

Indications for Use *(Describe)*
The Fogarty Graft Thrombectomy Catheter is indicated for use in adult patients for the removal of organized thrombus and adherent non-thrombotic material from synthetic bypass grafts, specifically synthetic arteriovenous grafts used for dialysis access and synthetic grafts for ileo-femoral bypass in the peripheral arterial vasculature. General indications for arterial reconstruction of an obstructed graft include disabling claudication, ischemic pain at rest, or ischemic skin lesions or gangrene. General indications for reconstruction of a synthetic AV fistula internal bridge graft include the inability to properly dialyse the patient.

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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K233619 510(K) SUMMARY

510(k) Submitter	Edwards Lifesciences, LLC One Edwards Way Irvine, CA, USA 92614	
Contact Person	**Primary Contact** Aeree Lee Sr. Manager, Regulatory Affairs Edwards Lifesciences LLC One Edwards Way, Irvine, CA 92614 Telephone: (949) 250-5155 Email: aeree_lee@edwards.com	**Secondary Contact** Karen O'Leary Sr. Director, Regulatory Affairs Edwards Lifesciences LLC One Edwards Way, Irvine, CA USA, 92614 Tel.: (949) 250-0715 Email: karen_oleary@edwards.com
Date Prepared	May 16, 2024	
Trade Name	Fogarty Corkscrew Catheters (140806, 140808, 1408010) Fogarty Graft Thrombectomy Catheters (160245F and 160246F)	
Regulation Number/ Regulation Name	21 CFR 870.5150; Embolectomy catheter	
Product Code	DXE	
Regulation Class	II	
Predicate Device	Fogarty Arterial Embolectomy II Catheters (K901625, cleared on July 06, 1990) Intramed® Graft Thrombectomy Instrument Set (K942457, cleared on February 07, 1995)	
Device Description	**Fogarty Corkscrew Catheters:** The Fogarty Corkscrew Catheters are sterile, single use flexible catheters consisting of a polyvinylchloride outer catheter body surrounding a movable, radiopaque stainless steel spring body. A second radiopaque, spiral-shaped, stainless steel cable covered by a latex membrane is attached to the distal end of the catheter. A handle to modulate the spiral cable diameter is attached to the inner spring body at the proximal end of the catheter. The spiral cable design of the Fogarty Corkscrew catheter increases the surface area for entrapping fibrous material. **Fogarty Graft Thrombectomy Catheters:** The Fogarty Graft Thrombectomy catheters are sterile, single use catheters designed to remove organized thrombus and adherent non-thrombotic material from synthetic bypass grafts, specifically synthetic arterial vasculature fistulas for	

	dialysis access and synthetic grafts for iliofemoral bypass. During use, the control button on the device handle is grasped and moved forward and aft to cause the spiral wires at the distal end to extend or retract. The spiral wires are extended during passage of the device through a narrowed region of a vessel. The spiral wires are then retracted to facilitate occlusive material removal.
Indications for Use	**Fogarty Corkscrew Catheters:** The Fogarty Corkscrew Catheter is indicated for use in adult patients with emboli/thrombi in the peripheral arterial vasculature in either native vessels or synthetic grafts. **Fogarty Graft Thrombectomy Catheters:** The Fogarty Graft Thrombectomy Catheter is indicated for use in adult patients for the removal of organized thrombus and adherent non-thrombotic material from synthetic bypass grafts, specifically synthetic arteriovenous grafts used for dialysis access and synthetic grafts for ileo-femoral bypass in the peripheral arterial vasculature. General indications for arterial reconstruction of an obstructed graft include disabling claudication, ischemic pain at rest, or ischemic skin lesions or gangrene. General indications for reconstruction of a synthetic AV fistula internal bridge graft include the inability to properly dialyse the patient.
Comparison to Predicate Device	The Fogarty Corkscrew and Graft Thrombectomy Catheters are substantially equivalent to their predicate devices. The subject devices' indications for use were clarified within the existing intended use and are similar to the predicate devices' indications for use. The Fogarty Corkscrew and Graft Thrombectomy Catheters have the same technological characteristics as their predicate devices, with the exception of minor modifications that have occurred to the design, materials, and device packaging. The differences do not raise any new questions of safety and effectiveness. The provided bench testing demonstrates the subject devices are substantially equivalent to the predicates.
Device Testing	Biocompatibility testing was performed in accordance with ISO 10993-1: 2018 – Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process, and FDA guidance document, Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process", issued on September 4, 2020. Bench testing was performed in accordance with Edwards' design requirements. In addition, shelf-life, packaging, and sterilization validations have been performed.
Conclusion	Based on the performance testing and the technological characteristics, the Fogarty Corkscrew and Fogarty Graft Thrombectomy Catheters meet the established performance criteria and are substantially equivalent to the predicate devices.