May 22, 2024

Edwards Lifesciences
Yagna Angirish
Sr. Regulatory Affairs Specialist
1 Edwards Way
Irvine, California 92614

Re: K233820
Trade/Device Name: Fogarty Arterial Embolectomy Catheter with Gate Valve
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: DXE
Dated: November 30, 2023
Received: December 1, 2023

Dear Yagna Angirish:

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: 2024.05.22 12:31:23 -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.

Submission Number *(if known)*

K233820

Device Name

Fogarty Arterial Embolectomy Catheter with Gate Valve

Indications for Use *(Describe)*

The Fogarty arterial embolectomy catheter with gate valve is indicated for use in adult patients for the removal of fresh, soft emboli and thrombi from vessels in the peripheral arterial 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

Fogarty Arterial Embolectomy Catheter with Gate Valve		
510(k) Submitter	Edwards Lifesciences, LLC One Edwards Way, Irvine, CA 92614 (949) 250-1119	
Contact Person	Primary Contact Yagna Angirish Sr. Specialist, Regulatory Affairs Edwards Lifesciences LLC One Edwards Way, Irvine, CA USA, 92614 Tel.: (949) 250-1119 Email: yagna_angirish@edwards.com	Secondary Contact Aeree Lee Sr. Manager, Regulatory Affairs Edwards Lifesciences LLC One Edwards Way, Irvine, CA USA, 92614 Tel.: (949) 250-5155 Email: aeree_lee@edwards.com
Date Prepared	May 20, 2024	
Trade Name	Fogarty Arterial Embolectomy Catheter with Gate Valve	
Regulation Number / Name	21 CFR 870.5150 / Embolectomy catheter	
Product Code	DXE	
Regulation Class	Class II	
Predicate Device	Preamendment Fogarty Arterial Embolectomy Catheter	
Device Description	The Fogarty Arterial Embolectomy Catheter with Gate Valve provides a means of clearing emboli and thrombi from vessels in the arteries of the peripheral vasculature through inflation of the balloon and engagement with the arterial wall beyond the vascular obstruction followed by gentle withdrawal of the catheter thereby removing the obstruction from its position. The device catheter size is 2F and is available in 45 cm length. The catheter contains a latex balloon at the distal end and a gate valve at the proximal end for connection to a syringe for balloon inflation.	
Indications for Use	The Fogarty Arterial Embolectomy Catheter with Gate Valve is indicated for use in adult patients for the removal of fresh, soft emboli and thrombi from vessels in the peripheral arterial vasculature.	
Comparative Analysis	The subject device is identical to the predicate device in terms of the intended use, indications for use, and technological characteristics (including design, material, chemical composition, principle of operation), except for a gate valve at the proximal end rather than a hub.	
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:	

Fogarty Arterial Embolectomy Catheter with Gate Valve	
	Evaluation and testing within a risk management process", issued on September 4, 2020. Bench testing was performed in accordance with Edwards' current design requirements. In addition, shelf-life, packaging, and sterilization validations have been performed to existing specifications. All testing met the existing predetermined acceptance criteria.
Conclusion	Based on the performance testing and the technological characteristics, the Fogarty Arterial Embolectomy Catheter with Gate Valve meets the established performance criteria and is substantially equivalent to the predicate device Fogarty Arterial Embolectomy Catheters.