July 2, 2024

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

Re: K241330
Trade/Device Name: Fogarty Fortis Arterial Embolectomy Catheter
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: DXE
Dated: May 10, 2024
Received: May 10, 2024

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 (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: 2024.07.02 15:15:44 -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)*

K241330

Device Name

Fogarty Fortis Arterial Embolectomy Catheter

Indications for Use *(Describe)*

The Fogarty Fortis Arterial Embolectomy Catheters are indicated for use in adult patients for the removal of fresh, soft emboli and thrombi from vessels in the peripheral arterial system.

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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# 510(K) SUMMARY

| **Fogarty Fortis Arterial Embolectomy Catheter** | | |
|---|---|---|
| 510(k) Submitter | Edwards Lifesciences, LLC<br>One Edwards Way<br>Irvine, CA 92614 | |
| Contact Person | Primary Contact<br>Aeree Lee<br>Sr. Manager, Regulatory Affairs<br>Edwards Lifesciences LLC<br>One Edwards Way,<br>Irvine, CA USA, 92614<br>Tel.: (949) 250-5155<br>Email: aeree_lee@edwards.com | Secondary Contact<br>Karen O'Leary<br>Sr. Director, Regulatory Affairs<br>Edwards Lifesciences LLC<br>One Edwards Way,<br>Irvine, CA USA, 92614<br>Tel.: (949) 250-0715<br>Email: karen_oleary@edwards.com |
| Date Prepared | July 1, 2024 | |
| Trade Name | Fogarty Fortis Arterial Embolectomy Catheter | |
| Regulation Number / Name | 21 CFR 870.5150 / Embolectomy catheter | |
| Product Code | DXE | |
| Regulation Class | Class II | |
| Predicate Device | Preamendment Fogarty Arterial Embolectomy Catheter (Preamendment status granted on May 20, 2020) | |
| Device Description | The Fogarty Fortis Arterial Embolectomy Catheters provide a means of clearing emboli and thrombi from vessels in the arteries of the peripheral system 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.<br><br>The device catheter size is 4F and are available in 40 cm and 80 cm lengths. The device consists of a radiopaque catheter shaft with an integrated elastomeric latex balloon and an atraumatic tip that is inserted surgically into arterial vessels of the peripheral system. A hub at the proximal end is used for balloon inflation. | |
| Indications for Use | The Fogarty Fortis Arterial Embolectomy Catheters are indicated for use in adult patients for the removal of fresh, soft emboli and thrombi from vessels in the peripheral arterial system. | |
| Comparative Analysis | The subject device is identical to the predicate device in terms of the intended use, indications for use, and technological characteristics, except for the catheter body tubing material and the balloon wall dimension to the subject device to allow for withstanding a greater pull-force. The differences do not raise any new concerns of safety and effectiveness. Verification for the subject devices demonstrate substantial equivalence to the predicates. 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 | |

| **Fogarty Fortis Arterial Embolectomy Catheter** | |
|---|---|
| | 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.<br><br>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.<br><br>All testing met the existing predetermined acceptance criteria. |
| Conclusion | Based on the performance testing and the technological characteristics, the Fogarty Fortis Arterial Embolectomy Catheters meet the established performance criteria and are substantially equivalent to the predicate Fogarty Arterial Embolectomy Catheters. |