June 12, 2020

Edwards Lifesciences, LLC
Wendy Gonzalez
Associate Manager, Regulatory Affairs
One Edwards Way
Irvine, California 92614

Re: K193379
Trade/Device Name: Fogarty Arterial Embolectomy Catheter, Fogarty Biliary Balloon Probe
Regulation Number: 21 CFR 870.5150 and 21 CFR 876.5010
Regulation Name: Embolectomy Catheter and Biliary Catheter and Accessories
Regulatory Class: Class II
Product Code: DXE, GCA
Dated: May 18, 2020
Received: May 20, 2020

Dear Ms. Gonzalez:

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 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193379

Device Name
Fogarty Arterial Embolectomy Catheter and Fogarty Biliary Balloon Probe

Indications for Use *(Describe)*

Fogarty Arterial Embolectomy Catheter:

The Fogarty Arterial Embolectomy Catheter is indicated for the removal of fresh, soft emboli and thrombi from vessels in the arterial system. To remove fibrous or adherent material, alternative devices such as the Fogarty Adherent Clot and Graft Thrombectomy Catheter are recommended.

Fogarty Biliary Balloon Probe:

The Fogarty Biliary Balloon Probe is indicated for the removal of stones and ductal debris and exploration.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) SUMMARY

Fogarty Arterial Embolectomy Catheter and Fogarty Biliary Balloon Probe		
510(k) Submitter	Edwards Lifesciences, LLC	
Contact Person	Wendy Vera González Associate Manager, Regulatory Affairs Edwards Lifesciences (949) 250- 2500	
Date Prepared	June 9, 2020	
Trade Name	Fogarty Arterial Embolectomy Catheter	Fogarty Biliary Balloon Probe
Regulation Description	Embolectomy Catheter	Biliary catheter and accessories
Regulation Class / Product Code	Class II DXE	Class II GCA
Predicate Device(s)	Pre-amendment	Pre-amendment
Regulation Number	21 CFR 870.5150	21 CFR 876.5010
Device Description	<u>Fogarty Arterial Embolectomy Catheter</u> The Fogarty Arterial Embolectomy Catheter consists of a catheter body tube made out of polyvinyl chloride (PVC) or nylon (3F only) of 40, 60, or 80 cm lengths. The catheter contains a latex balloon at the distal end and a PVC hub at the proximal end for connection to a syringe for balloon inflation. They contain a soft, rounded tip, which promotes easy arterial insertion. The model with an "S" has a stylet at the proximal end to support the inflation lumen during shipping and storage. These devices are provided sterile and labeled for single use only.	

	<u>Fogarty Biliary Balloon Probe</u> The Fogarty Biliary Balloon Probe consists of a single-lumen polyvinyl chloride (PVC) catheter body with a latex balloon at the distal end. A hub at the proximal end is used for balloon inflation. A flexible stylet is provided with Fogarty Biliary Balloon Probe. The stylet is of a designed stiffness intended to avoid perforation and yet maintain enough shape to facilitate introduction of the probe into areas of sharp angulation. These devices are provided sterile and labeled for single use only. The Fogarty Biliary Balloon Probe is not intended to be used with other devices.
Indications for Use/Intended Use	The Fogarty Arterial Embolectomy Catheter is indicated for the removal of fresh, soft emboli and thrombi from vessels in the arterial system. To remove fibrous or adherent material, alternative devices such as the Fogarty Adherent Clot and Graft Thrombectomy Catheter are recommended. The Fogarty Biliary Balloon Probe is indicated for the removal of stones and ductal debris and exploration.
Comparative Analysis	The subject device is identical to the predicate devices in terms of intended use, indications for use, and technology. The proposed changes involve the creation of new model numbers for the existing legally marketed device with a new packaging configuration, new labels and updates to the IFU as a result of the new model numbers. Packaging design verification, sterilization (EO resistance and residuals), product performance and biocompatibility evaluations were conducted to ensure that the change in final packaging did not alter the performance of the subject devices. The subject Fogarty Arterial Embolectomy Catheter and Fogarty Biliary Balloon Probe, have been shown to be substantially equivalent to the predicate devices for its intended use in hospitals and other appropriate clinical environments.
Functional/ Safety Testing	The Fogarty Arterial Embolectomy Catheter and Fogarty Biliary Balloon Probe with new packaging configuration are identical to the predicate device in terms of final device and indications for use. To ensure that the Fogarty Arterial Embolectomy Catheter and Fogarty Biliary Balloon Probe with new packaging configuration did not raise any new concerns of safety and effectiveness, and are substantially equivalent to the predicate devices, the following evaluation and testing were performed: ➢ Product Performance testing evaluation and Product Test /Balloon Inflation test to demonstrate final device is not affected.

	➢ Packaging testing in accordance to ISO 11607-1 – Packaging for Terminally Sterilized Medical Devices. ➢ Sterilization testing in accordance to ISO 11135:2014 - Sterilization of health-care products- Ethylene oxide- Requirements for the development, validation and routing control of a sterilization process for medical devices. ➢ EO/ ECH residuals evaluation in accordance to ISO10993-7:2008 – Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals. The Fogarty Arterial Embolectomy Catheter and Fogarty Biliary Balloon Probe models have successfully passed performance, packaging, sterility assurance and EO/ECH residuals testing demonstrating that the subject devices are substantially equivalent to the predicate devices.
Conclusion	The Fogarty Arterial Embolectomy Catheter and Fogarty Biliary Balloon Probe are substantially equivalent to the predicate device.