February 14, 2022

Edwards Lifesciences, LLC
Anisha Butala
Regulatory Affairs Specialist
One Edwards Way
Irvine, California 92614

Re: K211610
Trade/Device Name: Fogarty Occlusion Catheter
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular Clamp
Regulatory Class: Class II
Product Code: MJN
Dated: January 13, 2022
Received: January 14, 2022

Dear Anisha Butala:

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,

for Carmen Gacchina Johnson, PhD
Assistant Director
DHT2B: Division of Circulatory Support,
Structural and Vascular 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)*
K211610

Device Name
Fogarty Occlusion Catheters

Indications for Use *(Describe)*
The Fogarty Occlusion Catheters are indicated for temporary vessel occlusion.

The Large Occlusion Catheters are intended to be used for temporary occlusion in the aorta, vena cava and internal jugular vein.

The Small Occlusion Catheters are intended to be used for temporary occlusion in the peripheral vascular 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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SECTION 5. 510(K) SUMMARY

Table 5-1: Summary Table

Fogarty Occlusion Catheters		
510(k) Submitter	Edwards Lifesciences, LLC One Edwards Way Irvine, CA, USA 92617	
Contact Person	**Primary Contact** Anisha Butala Specialist, Regulatory Affairs Edwards Lifesciences One Edwards Way Irvine, CA 92614 Telephone: (949) 250-1004 Fax: (949) 809-2954 Email: Anisha_Butala@edwards.com	**Secondary Contact** Karen O'Leary Director, Regulatory Affairs Edwards Lifesciences One Edwards Way Irvine, CA 92614 Telephone: (949) 250-0715 Fax: (949) 809-2954 Email: Karen_OLeary@edwards.com
Date Prepared	February 14, 2022	
Trade Name	**Fogarty Occlusion Catheters**	
Common Name	Vascular Occlusion Balloon Catheter	
Classification Name	MJN – Catheter, Intravascular Occluding, Temporary	
Regulation Class/Product Code	21 CFR 870.4450/MJN	
Predicate Device(s)	Fogarty Occlusion Catheter, K152762, (SE November 23, 2015)	
Device Description	**Models: 620403F, 620404F, and 620405F** The Fogarty Small Occlusion Catheters (4F, 5F) consist of a single-lumen polyvinylchloride catheter body with a latex balloon at the distal end and a gate valve at the proximal end. The 3F Fogarty Occlusion Catheter is made of Nylon. The catheter lumen is used for inflation of the balloon via a syringe connected to the gate valve. A removable stainless-steel stylet is provided with each catheter to maintain the straight catheter shape and to ensure that the lumen remains opened during storage of the product. **Models: 62080814F and 62080822F** The Fogarty 8F Large Occlusion Catheters consist of a single-lumen polyvinylchloride catheter body with a latex balloon at the distal end and a gate valve at the proximal end. The catheter lumen is used for inflation of the balloon via a syringe connected to the gate valve. A removable stainless-steel stylet is provided with each catheter.	
Indications for Use/Intended Use	Fogarty Occlusion Catheters are intended for temporary vessel occlusion. **Models: 620403F, 620404F, and 620405F** The Small Occlusion catheters are intended to be used for temporary occlusion in the peripheral vascular system. **Models: 62080814F and 62080822F**	

	The Large Occlusion catheters are intended to be used for temporary occlusion in the aorta, vena cava and internal jugular vein.
Comparative Analysis	The subject device is identical to the predicate device, K152762 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 devices with a new alternative 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 testing evaluations were conducted to ensure that the change in the new alternative final packaging did not alter the performance of the subject devices. The subject Fogarty Occlusion Catheters 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 Occlusion Catheters with new alternative packaging configuration are identical to the predicate device in terms of the final device and indications for use. To ensure that the Fogarty Occlusion Catheters with new alternative 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 testing. ➢ 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 Occlusion Catheters 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 Occlusion Catheters are substantially equivalent to the predicate devices, K152762.