



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

November 23, 2015

Edwards Lifesciences, LLC.
Naren Murugan
Regulatory Affairs Associate II
One Edwards Way
Irvine, California 92614

Re: K152762
Trade/Device Name: Fogarty Occlusion Catheter
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular Clamp
Regulatory Class: Class II
Product Code: MJN
Dated: September 23, 2015
Received: September 24, 2015

Dear Naren Murugan:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Kenneth J. Cavanaugh -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K152762

Device Name
Fogarty Occlusion Catheter

Indications for Use (Describe)
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.

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5.0 TRADITIONAL 510(K) SUMMARY

Submitted by:	Edwards Lifesciences, LLC.
Contact Person:	Naren Murugan Edwards Lifesciences One Edwards Way Irvine, CA Direct Line: 949-250-2861 email: Naren_murugan@edwards.com
Date of Summary:	September 23, 2015
Device Trade Name:	Fogarty Occlusion Catheter
Product Code:	MJN
Common or Usual Name:	Vascular Occlusion Balloon Catheter
Classification Name:	Vascular Clamp (21 CFR 870.4450)
Predicate Device(s):	Fogarty Occlusion Catheter, Pre-amendment device Fogarty Occlusion Catheter, K093911 (SE, 21January 2010)
Device Description:	<p>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. The catheter consists of a single-lumen polyvinylchloride (PVC) 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 to maintain the straight catheter shape and to ensure that the lumen remains opened during storage or sterilization of the product. The device is supplied sterile and for single use only.</p> <p>This Traditional 510(k) is submitted to request clearance for changes to the indications for use statement. The proposed changes to the indications for use statement do not alter the intended use of the Fogarty Occlusion Catheter (i.e., temporary vessel occlusion).</p>

Indication for Use:	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.
Technological Characteristics:	The technological characteristics of the Fogarty Occlusion Catheter are identical to those of the predicate (the current legally marketed version of the Fogarty Occlusion Catheter) in terms of the following:
	<ul style="list-style-type: none">• Size and shape;• Mode of Operation and Intended Use;• Target population;• Fundamental scientific technology;• Patient-contacting materials; and,• Method of delivery.
Performance Testing Summary:	The only change made is a change to the indications for use statement, resulting in a revision to the Instructions for Use. An analysis was performed to evaluate these changes and it was determined that the specific vessels identified for each size catheter would be expected to have similar safety and effectiveness compared to the general indications for the predicate.
	The device with the proposed change to the indication for use statement has the identical design, materials, technology, and operating principles as the current legally marketed version of the device, and as such no performance testing was conducted.
	The current legally marketed version of the Fogarty Occlusion Catheter complies with all applicable design practices and regulations and was most recently cleared by FDA via K093911(SE 21 Jan 2010) for modifications of its packaging.
Conclusion:	The technology of the Fogarty Occlusion Catheter is identical to the named predicate and the changes to the indications for use do not change the intended use or the adversely impact safety and effectiveness. Therefore, the Fogarty Occlusion Catheter is substantially equivalent to the predicate.
