June 5, 2026

Marcelo Piovarcsik
Senior Specialist, Regulatory Affairs
Edwards Lifesciences
One Edwards Way
Irvine, California 92614

Re: K260105
Trade/Device Name: Fogarty Spring Clips, Handleless Clamps, and Clamp Inserts
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular Clamp
Regulatory Class: Class II
Product Code: DXC
Dated: January 13, 2026
Received: January 13, 2026

Dear Marcelo Piovarcsik:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

VICTOR MONDINE -S 2026.06.05 12:58:03 -04'00'

for Katherine Trivedi
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K260105

Device Name
Fogarty Spring Clips, Handleless Clamps, and Clamps Inserts

Indications for Use *(Describe)*
The Fogarty Spring Clips and Handleless Clamps are indicated for both artery and vein vessel occlusion in adult surgical patient populations.

The Fogarty Clamp Inserts are indicated to support the occlusion of veins and arteries without excessive clamping forces for adult patients undergoing surgical procedures.

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 Spring Clips, Handleless Clamps, and Clamps Inserts

510(k) Submitter	Edwards Lifesciences, LLC One Edwards Way Irvine, CA, USA 92614	
Contact Person	Primary Contact: Marcelo Piovarcsik Sr. Specialist, Regulatory Affairs Edwards Lifesciences One Edwards Way Irvine, CA 92614 Email: Marcelo.Piovarcsik@bd.com	Secondary Contact: Aditi Iyengar Sr. Manager, Regulatory Affairs Edwards Lifesciences One Edwards Way Irvine, CA 92614 Email: Aditi.Iyengar@bd.com
Date Prepared	May 8, 2026	
Trade Name	Fogarty Spring Clips, Handleless Clamps, and Clamps Inserts	
Regulation Number / Regulation Name	21 CFR 870.4450 / Vascular clamps	
Product Code	DXC	
Regulation Class	Class II	
Predicate Device	Fogarty Spring Clips, Handleless Clamps, and Clamps Inserts (K832554 and Preamendment)	
Device Description	The Fogarty spring clips and handleless clamps provide a means of occlusion pressure to control the flow of circulating blood. The Fogarty spring clips and handleless clamps are intended for atraumatic vessel occlusion. The Fogarty clamp inserts provide a means of occlusion pressure to control the flow of circulating blood. The Fogarty clamp inserts are intended for atraumatic vessel occlusion. The devices function by applying a controlled compressive force through opposing jaws, achieving temporary vascular occlusion without causing trauma to the vessel wall. This force is generated manually by a clinician and maintained either by the inherent spring tension in the Spring Clips or by the ratchet mechanism in the Handleless Clamps. The devices are available in multiple jaw configurations, lengths, and surface finishes such as smooth, serrated, and combination designs, allowing clinicians to select the most appropriate option based on vessel size, location, and occlusion requirements. The Fogarty Spring Clips have jaw openings from 6 mm to 12 mm. The clips offer various jaw surfaces and sizes to accommodate inserts that provide compliant occlusion or enhanced traction. Fogarty Handleless Clamps feature jaw openings of 8 mm to 10 mm and have specialized jaw surfaces for secure yet atraumatic occlusion. Fogarty Clamp Inserts, available in lengths of 33 mm, 61 mm, and 86 mm, provide a unique grasping principle through replaceable jaw inserts (e.g., Hydrajaw, Softjaw, Safejaw, EverGrip, Tractionjaw). These inserts evenly	

	distribute pressure while maintaining adequate traction and used with compatible spring clips and clamps.
Indications for Use	Fogarty Spring Clips and Handleless Clamps: The Fogarty Spring Clips and Handleless Clamps are indicated for both artery and vein vessel occlusion in adult surgical patient populations. Fogarty Clamp Inserts: The Fogarty Clamp Inserts are indicated to support the occlusion of veins and arteries without excessive clamping forces for adult patients undergoing surgical procedures.
Comparison to Predicate Device	The subject Fogarty Spring Clips, Handleless Clamps, and Clamps Inserts are substantially equivalent to the 510(k) cleared (K832554) and preamendment Fogarty Spring Clips, Handleless Clamps, and Clamps Inserts. The Fogarty Spring Clips, Handleless Clamps, and Clamps Inserts have the same intended use and technological characteristics as the predicate devices. There are no significant differences that raise any new concerns of safety and effectiveness. Bench testing, inclusive of design verification, packaging, sterilization, and biocompatibility testing all demonstrate that the subject devices are substantially equivalent to the predicate devices.
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: Evaluation and testing within a risk management process", issued on September 4, 2020. Bench testing was performed in accordance with internal 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 Spring Clips, Handleless Clamps, and Clamps Inserts meet the established performance criteria and have been shown to be substantially equivalent to the predicate devices.