August 22, 2022

Edwards Lifesciences, LLC
Mahvish Iqbal
Senior Specialist, Regulatory Affairs
One Edwards Way
Irvine, California 92614

Re: K221528
Trade/Device Name: Fogarty Dilation Atrioseptostomy Catheter, Miller Balloon Atrioseptostomy Catheter
Regulation Number: 21 CFR 870.5175
Regulation Name: Catheter, Septostomy
Regulatory Class: Class II
Product Code: DXF
Dated: May 25, 2022
Received: May 26, 2022

Dear Mahvish Iqbal:

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,

Rachel Neubrander
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)*
K221528

Device Name
Fogarty Dilation Atrioseptostomy Catheter
Miller Balloon Atrioseptostomy Catheter

Indications for Use *(Describe)*
The Fogarty dilation atrioseptostomy catheter is indicated for enlarging interatrial openings for palliation of several congenital cardiac defects to increase mixing at atrial level or to decompress a hypertensive atrial chamber.

The Miller balloon atrioseptostomy catheter is indicated for enlarging interatrial openings for palliation of several congenital cardiac defects to increase mixing at atrial level or to decompress a hypertensive atrial chamber.

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."*

Edwards

# 510(k) Summary

**Submitter:** Edwards Lifesciences LLC
One Edwards Way
Irvine, CA 92614
(949) 250-2500

**Contact:** Mahvish Iqbal Phone: (949) 250-4994, Fax: (949) 809-5655

**Prepared:** August 22, 2022

**Trade Name:** Fogarty Dilation Atrioseptostomy Catheter, Model 830705F and Miller Balloon Atrioseptostomy Catheter, Model 830515F

**Common Name:** Atrioseptostomy Catheter

**Classification:** Catheter, Septostomy
21 CFR 870.5175, Product Code DXF

**Predicate Device:** Fogarty Dilation Catheter for Atrial Septostomy, Model 83-05-05F (Preamendment)

**Device Description:**

The Fogarty dilation atrioseptostomy catheter is a 5 French single-lumen catheter (with 8F uninflated balloon OD) with a wire-wound shaft that may be visualized using fluoroscopy. A latex balloon with a maximum inflated diameter of 15mm is located at the distal end of the catheter. The distal tip has a nominal angulation of 35° to facilitate manipulation of the balloon through the inter-atrial opening. A removable stylet is provided to increase catheter body stiffness and for temporary straightening of the 35° tip angulation during insertion. The catheter contains a gate valve in order to inflate and deflate the balloon. The catheter shaft has depth markings in 10 cm spacing.

The Miller balloon atrioseptostomy catheter is a 5 French single-lumen catheter (with 9F uninflated balloon OD) with a wire-wound shaft that may be visualized using fluoroscopy. A latex balloon with a maximum inflated diameter of 19mm is located at the distal end of the catheter. The distal tip has a nominal angulation of 35° to facilitate manipulation of the balloon through the inter-atrial opening. A removable stylet is provided to increase catheter body stiffness and for temporary straightening of the 35° tip angulation during insertion. The catheter contains a gate valve in order to inflate and deflate the balloon. The catheter shaft has depth markings in 5 cm spacing. The Miller catheter contains a plug for occluding the vein or percutaneous sheath to reduce venous leakage.

The Fogarty dilation atrioseptostomy catheter and Miller balloon atrioseptostomy catheter are packaged in an identical tube configuration.

**Intended Use:**

The Fogarty dilation atrioseptostomy catheter and Miller balloon atrioseptostomy catheter are intended for use in atrioseptostomy procedures.

**Indication:**

The Fogarty dilation atrioseptostomy catheter is indicated for enlarging interatrial openings for palliation of several congenital cardiac defects to increase mixing at atrial level or to decompress a hypertensive atrial chamber.

The Miller balloon atrioseptostomy catheter is indicated for enlarging interatrial openings for palliation of several congenital cardiac defects to increase mixing at atrial level or to decompress a hypertensive atrial chamber.

**Comparison to Predicate:**

The Fogarty dilation and Miller balloon atrioseptostomy catheters are substantially equivalent to the predicate device. The subject devices' indications for use were clarified within the existing intended use and are similar to the preamendment device's indications for use. The subject devices have the same intended use as the predicate device.

The Fogarty dilation atrioseptostomy catheter has the same technological characteristics as the predicate device with the exception of minor modifications to the device packaging. The Miller balloon atrioseptostomy catheter has a larger balloon size, greater inflation volume and longer deflation time compared to the predicate device. These minor device differences do not introduce new issues of safety or effectiveness. The provided bench testing demonstrates the subject devices are substantially equivalent to the predicate.

**Summary of Non-Clinical Testing:**

Performance testing for the Fogarty dilation and Miller balloon atrioseptostomy catheters included the following:

- Design Verification
    - Visual/Dimensional Inspection
        - Catheter length
        - Catheter tip angle
        - Depth marker spacing
    - Balloon nominal diameter
    - Balloon pull force
    - Deflation time
    - Introducer compatibility
    - Joint strength testing
    - Air Leakage
- Biocompatibility

In addition, Edwards has performed sterilization, shelf life and packaging (bubble leak) validations.

**Edwards Lifesciences LLC**
One Edwards Way · Irvine, CA USA · 92614
Phone: 949.250.2500 · Fax: 949.250.2525 · www.edwards.com

**Conclusion:**

Based on the performance testing and the technological characteristics, the Fogarty dilation atrioseptostomy catheter and Miller balloon atrioseptostomy catheter meet the established performance criteria and are substantially equivalent to the predicate device.

**Edwards Lifesciences LLC**
One Edwards Way · Irvine, CA USA · 92614
Phone: 949.250.2500 · Fax: 949.250.2525 · www.edwards.com