December 17, 2023

Acutus Medical, Inc.
% Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K233691
Trade/Device Name: FlexCath Cross™ Transseptal Solution
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter introducer
Regulatory Class: Class II
Product Code: DYB
Dated: November 16, 2023
Received: November 16, 2023

Dear Prithul Bom:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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.

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,

Rachel E. Neubrander -S

Rachel Neubrander, PhD
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.

Submission Number *(if known)*

K233691

Device Name

FlexCath Cross™ Transseptal Solution

Indications for Use *(Describe)*

The FlexCath Cross™ Transseptal Solution is indicated to puncture the interatrial septum to gain access to the left side of the heart whereby various cardiovascular catheters are introduced.

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

General Information [807.92(a)(1)]

Date Prepared: October 6, 2023

Applicant:	Contact Person:
Acutus Medical, Inc. 2210 Faraday Ave., Suite 100 Carlsbad, CA 92008 USA Phone: 1-442-232-6080 Fax: 1-442-232-6081	Sarah Clay Senior Regulatory Affairs Specialist Acutus Medical, Inc. 2210 Faraday Ave., Suite 100 Carlsbad, CA 92008 USA Phone: 1-442-232-6080 Email: Sarah.clay@acutus.com

Device Information [807.92(a)(2)]

Trade Name:	FlexCath Cross™ Transseptal Solution
Generic/Common Name:	Dilator/Transseptal Needle
Classification:	Class II / 21 CFR § 870.1340
Product Code(s):	DYB, DRE

Predicate Device [807.92(a)(3)]

Predicate Device	Manufacturer	FDA 510(k)
AcQCross™ Qx Integrated Transseptal Dilator/Needle	Acutus Medical	K210685

Device Description [807.92(a)(4)]

FlexCath Cross™ combines the conventional vessel dilator and transseptal needle into a single device (Figure 1). FlexCath Cross™ consists of an elongated shaft with a tapered tip and central lumen to track over a guidewire. The lumen of FlexCath Cross™ is fitted with a hollow stainless steel transseptal needle (Figure 2). Both the shaft and needle are connected to the proximal handle of FlexCath Cross™. The lumen of the needle will allow for guidewires up to 0.032“ in diameter. The needle is affixed to a spring-tensioned actuator in the handle of FlexCath Cross™ that prevents needle extension until the operator purposely advances the needle via a slider button located on the outer surface of the handle. The proximal handle is fitted with a Luer connector to gain access to the central lumen of the needle. The handle is also fitted with an electrical connector that allows for monitoring intracardiac electrograms (EGMs) from the needle while in the heart utilizing the EGM adapter cable, and/or allows for the application of radiofrequency (RF) current from an electrosurgical generator to facilitate the septal puncture utilizing the ES adapter cable. FlexCath Cross™ is for single-use only and is provided sterile.

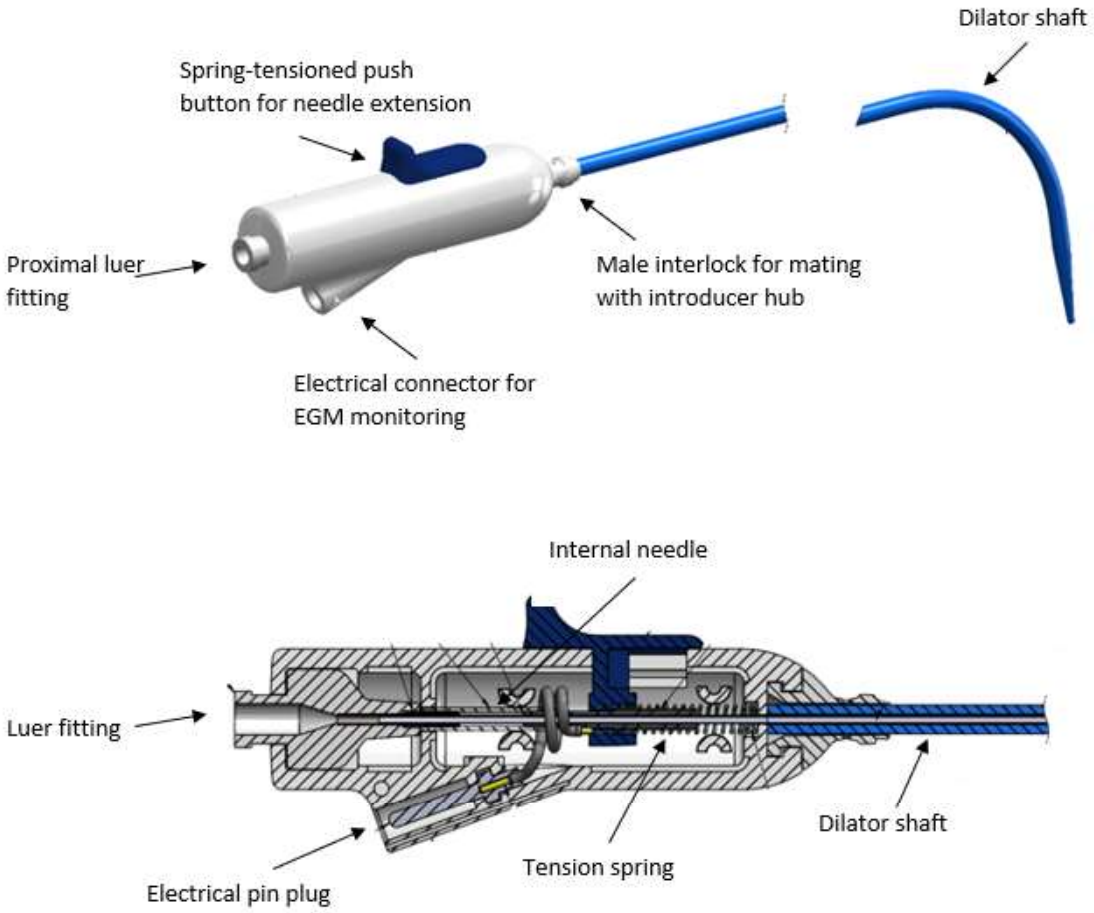


Figure 1: FlexCath Cross™ Integrated Transseptal Dilator/Needle

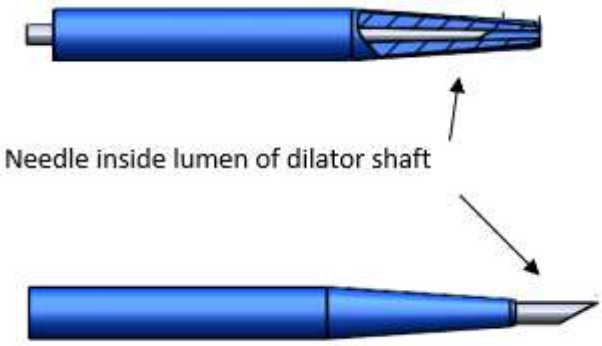


Figure 2: FlexCath Cross™ Needle inside lumen of dilator shaft

FlexCath Cross™ is designed to be compatible with certain commercially available transseptal sheaths. The new models of FlexCath Cross™ were added to provide the physician with additional sheath selection

for transseptal crossing. Table 1 lists the new models of FlexCath Cross™ for which Acutus Medical, Inc. is seeking clearance.

Table 1: FlexCath Cross™ Model Numbers			
Product (Subject Device)	Acutus Model Number	Compatible Sheath configurations	Medtronic Model Number
FlexCath Cross™ – FCC 10F– 65cm	900310	Medtronic FlexCath Contour 10F 13mmTip	10FCC13
		Medtronic FlexCath Contour 10F 20mmTip	10FCC20
FlexCath Cross™ – FCC 12F – 65cm	900311	Medtronic FlexCath Contour 12F 13mmTip	12FCC13
		Medtronic FlexCath Contour 12F 20mmTip	12FCC20

Indications for Use [807.92(a)(5)]

The FlexCath Cross™ Transseptal Solution is indicated to puncture the interatrial septum to gain access to the left side of the heart whereby various cardiovascular catheters are introduced.

Comparison of Technological Characteristics with the Predicate Devices [807.92(A)(6)]
Tables 2 provides a comparison of the additional models of the FlexCath Cross™ Transseptal Solution and indications for use against the predicate device.

Table 2: Predicate Device Comparison		
Characteristics	Predicate Device	Subject Device
	AcQCross Cross™ Qx Integrated Transseptal Dilator/Needle(K210685)	FlexCath Cross™ Transseptal Solution
Classification	Class II	Identical to K210685.
Regulation	21 CFR § 870.1340, Catheter Introducer	Identical to K210685.
Product Code	DYB, DRE	Identical to K210685.
Indications for Use	To puncture the interatrial septum to gain access to the left side of the heart whereby various cardiovascular catheters are introduced.	Identical to K210685.
Patient Anatomy	Intracardiac Structures	Identical to K210685.
Testing to Support Substantial Equivalence	Verification Testing, Validation Testing	Identical to K210685.
Physical Characteristics		
Key Components	• Elongated shaft with tapered tip and central lumen to track over guidewire. • Hollow stainless steel transseptal needle. Shaft and needle connected to proximal handle. • Needle affixed to a spring tensioned actuator which prevents needle extension	Identical to K210685.

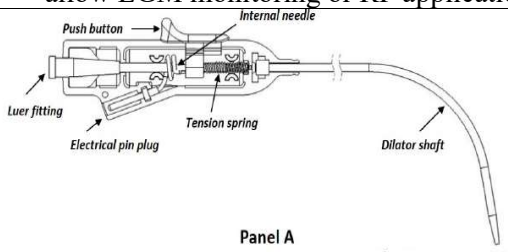
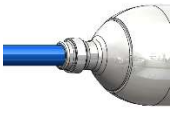
Table 2: Predicate Device Comparison		
Characteristics	Predicate Device AcQCross Cross™ Qx Integrated Transseptal Dilator/Needle(K210685)	Subject Device FlexCath Cross™ Transseptal Solution
	until operator advances needle via slider button located on the outer surface of handle. • Proximal handle fitted with luer connector to gain access to central lumen of needle. • Handle fitted with electrical connector to allow EGM monitoring or RF application.	
Product Diagram	 Panel A	Identical to K210685.
Dimensions	Needle effective length: 90.4cm ± .10cm Dilator effective length: 83.5cm ± 2.0cm French sizes compatible: 8.5F, 12F Guidewire sizes: up to .032”	Needle effective length: 90.4cm ± .10cm Dilator effective length: 83.5cm ± .25cm French sizes compatible: 10F, 12F Guidewire sizes: up to .032” Dimensions modified for new models to be compatible with associated sheaths. These minor dimensional differences are within the predicate device ranges and do not potentially impact the safety and effectiveness.
Handle lock feature	Handle tip shape modified to be compatible with each compatible sheath. 	Handle tip shape modified to be compatible with each compatible sheath.  **FlexCath Contour** Handle tip shape is uniquely modified to be compatible with each sheath's proximal hub. Minor differences in tip

Table 2: Predicate Device Comparison		
Characteristics	Predicate Device	Subject Device
	AcQCross Cross™ Qx Integrated Transseptal Dilator/Needle(K210685)	FlexCath Cross™ Transseptal Solution
		shape do not potentially impact safety and effectiveness
Material	Shaft: Polyethylene Hexene Copolymer; ethylene homopolymer; barium sulfate with blue colorant Needle: 304 Stainless steel Hypotube: 304 stainless steel Luer fitting: polycarbonate	Identical to K210685.
Packaging	Pouch: Tyvek® 1073B Uncoated, Nylon Film Backer card: High Density Polyethylene (HDPE) Shelf Box: Solid bleach sulfate paperboard Shipper: paperboard	Identical to K210685.
Sterilization	Ethylene Oxide (EO)	Identical to K210685.
Shelf Life	24 months	Identical to K210685.

Substantial Equivalence
FlexCath Cross™ is made of identical patient contacting materials and has minimal design modifications as referenced in Table 2 to that of the predicate device. FlexCath Cross™ performs as intended and presents no unacceptable risks to the intended patient population or end user. The non-clinical bench data support the safety of the device and demonstrate that FlexCath Cross™ performs as intended in the specified use conditions. The additional FlexCath Cross™ models do not raise any new questions regarding safety or effectiveness of the device as compared to the predicate device. The nonclinical tests demonstrate that the device is as safe and effective as the predicate device.

Performance Data [807.92(b)]
All necessary bench testing was conducted on the additional models FlexCath Cross™ to support a determination of substantial equivalence to the predicate device.

Non-clinical Testing Summary [807.92(b)(1)]

Bench Testing
The necessary bench testing was performed on the additional models of FlexCath Cross™ to ensure that it conforms to the design specifications and to support a determination of substantial equivalence to the predicate device.

Other than the following modifications, the additional models of FlexCath Cross™ are identical to that of the predicate device, AcQCross™ Qx(K210685). Therefore, the testing was performed on the subject device which focused on the safety and performance related to the modifications.
These modifications are limited to dimensional changes which facilitate compatibility with different transseptal sheaths and are as follows:

- Dilator shaft diameter
- Handle lock feature
- Colorant update to non-patient contacting handle components align with Medtronic branding

FlexCath Cross™ and the predicate device are otherwise identical in terms of materials, dimensions, packaging, shelf-life and sterilization. Therefore, performance testing has been leveraged from AcQCross™ Qx(K210685) for the subject device. The following performance testing was conducted in support of the substantial equivalence determination:

- Dimensional Inspection
- Shaft to handle tensile
- Length compatibility
- Snap engagement
- Kink resistance
- Needle actuation
- Visual inspection
- Aspiration/flushing
- Electrical continuity
- Sheath compatibility: Insertion/withdrawal

The collective bench testing demonstrates that the proposed device does not raise different questions of safety or effectiveness when compared to the predicate device.

Biocompatibility
Biocompatibility testing was performed on the predicate device K210685 in accordance with AAMI/ANSI/ISO 10993-1:2009 - Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process. The subject models of FlexCath Cross™ are made of identical patient contacting materials to the predicate device. Therefore, the previously submitted biocompatibility testing in K210685 has been leveraged for the subject device, and no additional biocompatibility testing is required.

Sterilization
Sterilization validation was performed on FlexCath Cross™ in accordance per ISO 11135: 2014 - Sterilization of health-care products- Ethylene Oxide- Requirements for development, validation and routine control of a sterilization process for medical devices. FlexCath Cross™ is subjected to the identical ethylene oxide (EO) sterilization process as the predicate device to meet a sterility assurance level (SAL) of 10^{-6}. The previously submitted sterilization validation of K210685 has been leveraged for the subject device. The new models have been adopted into the existing process per AAMI TIR28, *Product Adoption and Process Equivalence for Ethylene Oxide Sterilization*, and requires no further process validation.

Electrical Safety and Electromagnetic Compatibility (EMC)
The modifications to the new models of FlexCath Cross™ do not impact EMC and Electrical Safety. Therefore, the previously submitted EMC and Electrical Safety testing of the predicate device, K210685, has been leveraged for the subject device. Testing was completed in accordance with ANSI/AAMI IEC 60601-1:2005, IEC 60601-1, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*, IEC 60601-1-2, *Medical electrical equipment – Part 1-2: General requirements for the basic safety and essential performance – Collateral standard: Electromagnetic*

compatibility – Requirements and tests, and IEC 60601-2-2, *Medical electrical equipment – Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories*.

Conclusions [807.92(b)(3)]

FlexCath Cross™ is made of identical patient contacting materials and has minimal design modifications as referenced in Table 2 to that of the predicate device. FlexCath Cross™ performs as intended and presents no unacceptable risks to the intended patient population or end user. The non-clinical bench data support the safety of the device and demonstrate that FlexCath Cross™ performs as intended in the specified use conditions. The additional FlexCath Cross™ models do not raise any new questions regarding safety or effectiveness of the device as compared to the predicate device. The nonclinical tests demonstrate that the device is as safe and effective as the predicate device.