February 8, 2022

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

Re: K220047
Trade/Device Name: AcQCross Qx Integrated Transseptal Dilator/Needle
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter introducer
Regulatory Class: Class II
Product Code: DYB, DRE
Dated: January 4, 2022
Received: January 5, 2022

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 (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)*

K220047

Device Name

AcQCross™ Qx Integrated Transseptal Dilator/Needle

Indications for Use *(Describe)*

The AcQCross™ Qx Integrated Transseptal Dilator/Needle 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.

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510(K) SUMMARY

510(k) Number: K220047

Date Prepared: February 8, 2022

Table 5.1: Submitter Information

Manufacturer: Acutus Medical 2210 Faraday Ave, Suite 100 Carlsbad, CA 92008 US FDA ERN: 3012120746	Manufacturer's Contact Person: Sarah Clay Regulatory Affairs Specialist Phone: (949)291-7811 Fax: (442) 232-6081 Email: sarah.clay@acutus.com

Table 5.2: Device Information

Trade Name	AcQCross™ Qx Integrated Transseptal Dilator/Needle
Common Name	Dilator/Transseptal Needle
Classification Name	Catheter Introducer
Regulation	21 CFR 870.1340
Product Code **Subsequent Product Code**	DYB DRE
Regulatory Classification:	Class II
Device Panel:	Cardiovascular

The new models of the Acutus AcQCross™ Qx Integrated Transseptal Dilator/Needle are substantially equivalent to the previously cleared predicate, AcQCross™ Qx Integrated Transseptal Dilator/Needle **(Table 5.3).** This device has not been subject to a design-related recall.

Table 5.3: Predicate Devices

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

The new models of AcQCross™ Qx are compatible with certain commercially available transseptal sheaths.

5.1 Device Description

AcQCross™ Qx combines the conventional vessel dilator and transseptal needle into a single device (**Figure 1**). AcQCross™ Qx consists of an elongated shaft with a tapered tip and central lumen to track over a guidewire. The lumen of AcQCross™ Qx is fitted with a hollow stainless steel transseptal needle **(Figure 2)**. Both the shaft and needle are connected to the proximal handle of AcQCross™ Qx. 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 AcQCross™ Qx 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. AcQCross™ Qx is for single-use only and is provided sterile.

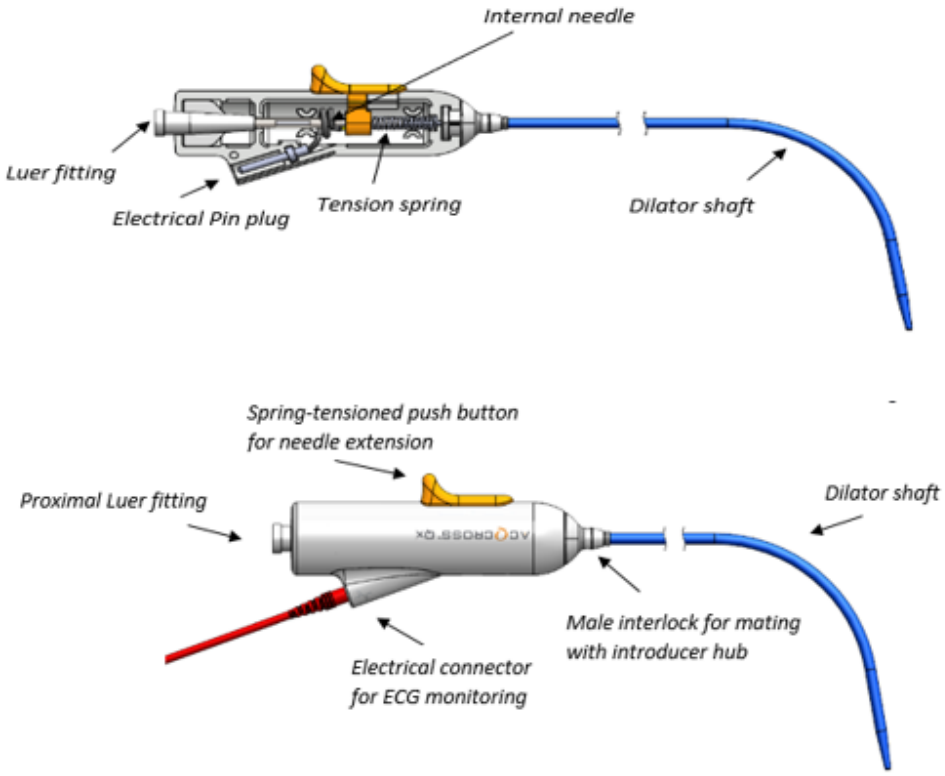


Figure 5.1: AcQCross™ Qx Integrated Transseptal Dilator/Needle

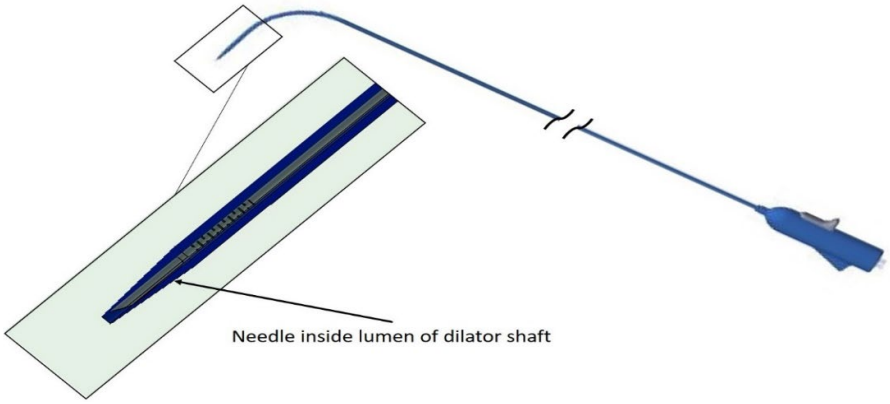


Figure 5.2: AcQCross™ Qx Needle inside lumen of dilator shaft

AcQCross™ Qx is designed to be compatible with certain commercially available transseptal sheaths. The new models of AcQCross™ were added to provide the physician with additional sheath selection for transseptal crossing. **Table 5.4** lists the new models of AcQCross™ Qx for which Acutus Medical, Inc. is seeking clearance.

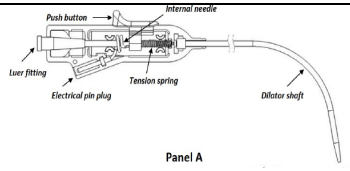
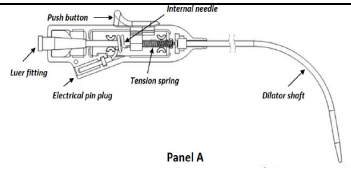
Table 5.4: AcQCross™ Qx Model Numbers

Product	Model Number	Compatible Sheath configurations	Model Number
AcQCross™ Qx – MH – 63cm	900306-001	Merit Medical ML Series (HeartSpan Transseptal) – 8.5F with 63cm working length	FCB8563ML1
AcQCross™ Qx – MH – 81cm	900307-001	Merit Medical ML Series (HeartSpan Transseptal) – 8.5F with 81cm working length	FCB8581ML1
AcQCross™ Qx – WT – 75cm	900308-001	Watchman TruSeal Access system – 12F with 75cm usable working length	M635TU70010 M635TU70020 M635TU70040
AcQCross™ Qx – SL – 81cm	900309-001	Abbott Braided Swartz SL Series – 8.5F with 81 usable working length	407454

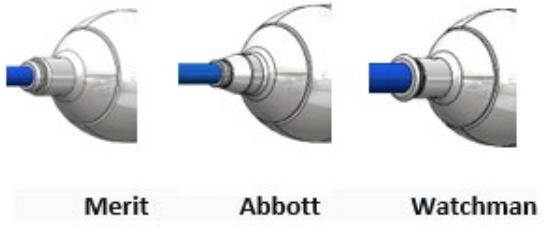
5.2 Indications for Use

The AcQCross™ Qx Integrated Transseptal Dilator/Needle is indicated to puncture the interatrial septum to gain access to the left side of the heart whereby various cardiovascular catheters are introduced.

5.3 Comparison of Technological Characteristics with the Predicate Device

Table 5.5: Substantial Equivalence Table- Regulatory Information			
Feature	**Proposed Device** **AcQCross™ Qx Integrated Transseptal Dilator/Needle(K_____)**	**Predicate Device** **AcQCross™ Qx Integrated Transseptal Dilator/Needle(K210685)**	**Analysis of Differences**
Classification	21 CFR 870.1340	21 CFR 870.1340	Identical to the predicate device.
Product Code **Subsequent Product Code**	DYB DRE	DYB DRE	Identical to the predicate device.
Product diagram			Identical to the predicate device.
Indications for Use Statement	To puncture the interatrial septum to gain access to the left side of the heart whereby various cardiovascular catheters are introduced.	To puncture the interatrial septum to gain access to the left side of the heart whereby various cardiovascular catheters are introduced.	Identical to predicate device.
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 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.	-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 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.	Identical to the predicate device.

<table>
<tr><th colspan="4">Table 5.5: Substantial Equivalence Table- Regulatory Information</th></tr>
<tr><th>Feature</th><th>Proposed Device
AcQCross™ Qx Integrated Transseptal Dilator/Needle(K_____)</th><th>Predicate Device
AcQCross™ Qx Integrated Transseptal Dilator/Needle(K210685)</th><th>Analysis of Differences</th></tr>
<tr><td></td><td>-Handle fitted with electrical connector to allow ECG monitoring or RF application.</td><td>-Handle fitted with electrical connector to allow ECG monitoring or RF application.</td><td></td></tr>
<tr><td>Dimensions</td><td>Needle effective length:
<table><tr><th>Model</th><th>Length</th></tr><tr><td>900306</td><td>74.15cm ± .10cm</td></tr><tr><td>900307</td><td>92.35cm ± .10cm</td></tr><tr><td>900308</td><td>91.36cm ± .10cm</td></tr><tr><td>900309</td><td>90.8cm ± .10cm</td></tr></table>Dilator effective length:
<table><tr><th>Model</th><th>Length</th></tr><tr><td>900306</td><td>67.3cm ± 2.0cm</td></tr><tr><td>900307</td><td>85.5cm ± 2.0cm</td></tr><tr><td>900308</td><td>84.5 cm ± 2.0cm</td></tr><tr><td>900309</td><td>85.6 cm ± 2.0cm</td></tr></table>French sizes compatible: 8.5F, 12F
Guidewire sizes: up to .032”</td><td>Needle effective length:
<table><tr><th>Model</th><th>Length</th></tr><tr><td>900302</td><td>74.6cm ± .10cm</td></tr><tr><td>900300, 900304</td><td>90.4cm ± .10cm</td></tr><tr><td>900301. 900303</td><td>100.3cm ± .10cm</td></tr><tr><td>900305</td><td>94.3cm ± .10cm</td></tr></table>Dilator effective length:
<table><tr><th>Model</th><th>Length</th></tr><tr><td>900302</td><td>67.7cm ± 2.0cm</td></tr><tr><td>900300, 900304</td><td>83.5cm ± 2.0cm</td></tr><tr><td>900301. 900303</td><td>93.4cm ± 2.0cm</td></tr><tr><td>900305</td><td>87.4cm ± 2.0cm</td></tr></table>French sizes compatible: 8.5F, 12F
Guidewire sizes: up to .032”</td><td>Dimensions modified for new models to be compatible with associated sheaths. These minor dimensional differences do not potentially impact the safety and effectiveness.</td></tr>
</table>

Table 5.5: Substantial Equivalence Table- Regulatory Information			
Feature	**Proposed Device** **AcQCross™ Qx Integrated Transseptal Dilator/Needle(K_____)**	**Predicate Device** **AcQCross™ Qx Integrated Transseptal Dilator/Needle(K210685)**	**Analysis of Differences**
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.  	Handle tip shape is uniquely modified to be compatible with each sheath's proximal hub. Minor differences in tip 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	Shaft: Polyethylene Hexene Copolymer; ethylene homopolymer; barium sulfate with blue colorant Needle: 304 Stainless steel Hypotube: 304 stainless steel Luer fitting: polycarbonate	Identical to predicate device.
Packaging	Pouch: Tyvek® 1073B Uncoated, Nylon Film Backer card: High Density Polyethylene (HDPE) Shelf Box: Solid bleach sulfate paperboard Shipper: paperboard	Pouch: Tyvek® 1073B Uncoated, Nylon Film Backer card: High Density Polyethylene (HDPE) Shelf Box: Solid bleach sulfate paperboard Shipper: paperboard	Identical to predicate device.
Sterilization	Ethylene Oxide (EO)	Ethylene Oxide (EO)	Identical to predicate device.
Shelf Life	12 months	12 months	Identical to predicate device.

5.4 Performance Data

Performance testing for AcQCross™ Qx and the predicate device, AcQCross™ Qx, was performed in accordance with the following standards.

- ISO 11070: 2014 – Sterile single-use intravascular introducers, dilators and guidewires
- ISO 10555-1: 2013 - Sterile, single-use intravascular catheters- Part 1: General Requirements

Other than the following modifications, the additional models of AcQCross™ Qx 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:

- Effective dilator length
- Effective needle length
- Handle lock feature

AcQCross™ Qx 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:

- Shaft to handle tensile
- Length compatibility
- Snap engagement
- Kink resistance
- Needle actuation
- Visual inspection
- Aspiration/flushing
- Electrical continuity

5.4.1 Biocompatibility

Biocompatibility testing was performed on the predicate device (K210685) AcQCross™ Qx 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 new models of AcQCross™ Qx are made of identical materials to the predicate device. Therefore, the previously submitted biocompatibility testing in K210685 has been leveraged for the subject device. No additional biocompatibility testing was required for the subject device.

5.4.2 Sterilization

Sterilization validation was performed on AcQCross™ Qx 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. AcQCross™ Qx 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.

5.4.3 Electrical Safety and Electromagnetic Compatibility (EMC)

The modifications to the new models of AcQCross™ Qx 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*.

5.4.4 Bench Testing

Due to the addition of new AcQCross™ Qx models compatible with certain compatible sheaths, AcQCross™ Qx was subject to the performance testing listed in **Section 5.4**. The subject models of AcQCross™ Qx and the predicate device are otherwise identical in terms of materials, dimensions, packaging, shelf-life and sterilization.

Therefore, the following performance testing has been leveraged from the predicate device (K210685) and no additional performance testing was required. Detailed justification is provided in **Section 18.**

- Dimensional Verification
- Surface Inspection
- Tip Curve Retention
- System Leak- Air Leakage- Luer Fitting
- Kink Resistance
- Shaft to Handle Tensile
- Needle to Button Tensile
- Luer to Hypotube Tensile
- Needle Actuation
- Electrical Continuity
- Pushability/Trackability in performance model
- Corrosion Resistance

- Radiopacity

5.5 Conclusions

AcQCross™ Qx is made of identical materials and has minimal design modifications as referenced in **Section 5.4** to that of the predicate device. AcQCross™ Qx 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 AcQCross™ Qx performs as intended in the specified use conditions. The additional AcQCross™ Qx models does not raise any new questions regarding safety or effectiveness of the device as compared to the predicate device. The nonclinical tests demonstrated that the device is as safe and effective as the predicate device.