April 6, 2021

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

Re: K210685
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
Dated: March 6, 2021
Received: March 8, 2021

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,

Jaime Raben -S

for 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)*

K210685

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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ACUTUS MEDICAL

510(K) SUMMARY

510(k) Number: K210685

Date Prepared: April 5, 2021

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 Associate 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	DYB
Regulatory Classification:	Class II
Device Panel:	Cardiovascular

The Acutus AcQCross™ Qx Integrated Transseptal Dilator/Needle is substantially equivalent to the previously cleared predicate, AcQGuide Catheter Introducer Sets **(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)
AcQGuide Catheter Introducer Sets w/ AcQCross™ Qx	Acutus Medical	K193509

AcQCross™ Qx was cleared under K193509, as part of the AcQGuide Catheter Introducer Sets (AcQGuide Flex® and AcQGuide Mini® Introducers with AcQCross™ Qx Dilator/Transseptal Needle), which are manufactured by Acutus Medical, Inc. Acutus Medical seeks clearance for AcQCross™ Qx as a standalone device in this submission, that can be used 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.

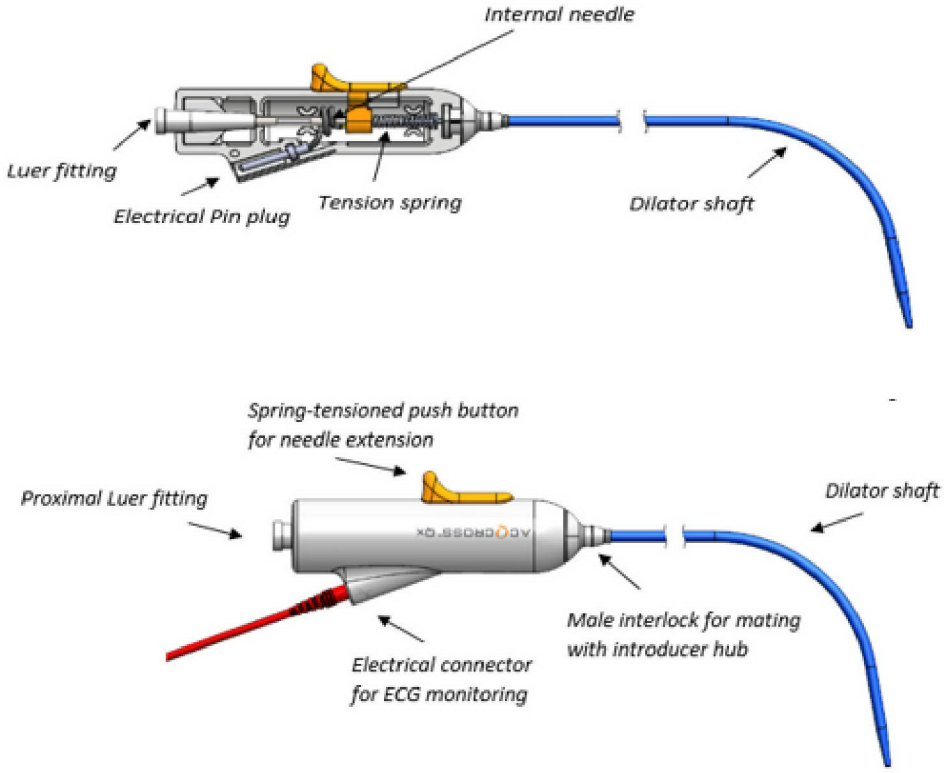


Figure 1: AcQCross™ Qx Integrated Transseptal Dilator/Needle

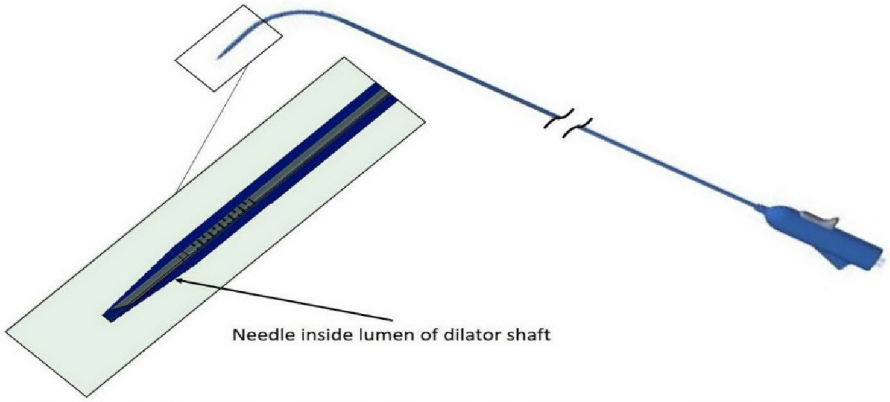


Figure 2: AcQCross™ Qx Needle inside lumen of dilator shaft

AcQCross™ Qx is designed to be compatible with certain commercially available transseptal sheaths. **Table 5.4** lists the AcQCross™ Qx variants for which Acutus Medical, Inc. is seeking clearance.

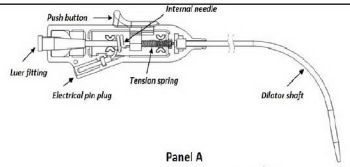
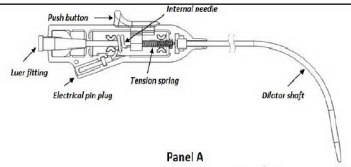
Table 5.4: AcQCross™ Qx Model Numbers

Product	Model Number	Compatible Sheath configurations	Model Number
AcQCross™ Qx – AG 61 cm	900300	Abbott Agilis NxT 8.5F steerable sheath – 61cm	G408318(SMALL CURL) G408319(MED CURL)
AcQCross™ Qx – AG 71 cm	900301	Abbott Agilis NxT 8.5F steerable sheath – 71cm	G408320(SMALL CURL) G408321(MED CURL) G408324(LARGE CURL)
AcQCross™ Qx – SL 63 cm	900302	Swartz SL1 8.5F fixed curve guiding sheath – 63cm	407453
AcQCross™ Qx – VZ 71 cm	900303	BSW Vizigo 8.5F bi-directional guiding sheath – 71cm	D138501(SMALL CURVE) D138502(MED CURVE) D138503(LARGE CURVE)
AcQCross™ Qx – FC 65 cm	900304	Medtronic FlexCath Advance 12F steerable sheath – 65cm	4FC12

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**(K210685)	**Predicate Device** **AcQGuide Catheter Introducer Sets (w/ AcQCross™ Qx) (K193509)**	**Analysis of Differences**
Classification	21 CFR 870.1340	21 CFR 870.1340	Identical to the predicate device.
Product Code	DYB	DYB	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.	Indicated for introducing various cardiovascular catheters into the heart, including the left side of the heart through the interatrial septum.	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.	-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.	Identical to the predicate device.

Feature	Proposed Device **AcQCross™ Qx Integrated Transseptal Dilator/Needle**(K210685)	Predicate Device **AcQGuide Catheter Introducer Sets (w/ AcQCross™ Qx) (K193509)**	Analysis of Differences
	-Proximal handle fitted with luer connector to gain access to central lumen of needle. -Handle fitted with electrical connector to allow ECG monitoring or RF application.	-Proximal handle fitted with luer connector to gain access to central lumen of needle. -Handle fitted with electrical connector to allow ECG monitoring or RF application.	
Dimensions	Needle length: Matched to Introducer French sizes compatible: 8.5F, 12F Guidewire sizes: up to .032”	Needle length: Matched to introducer French sizes compatible: 8.5F Guidewire sizes: up to .032”	Similar dimensions to predicate device. These minor differences do not potentially impact the 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.

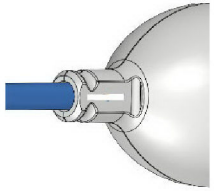
5.4 Performance Data

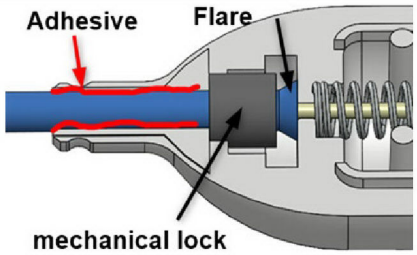
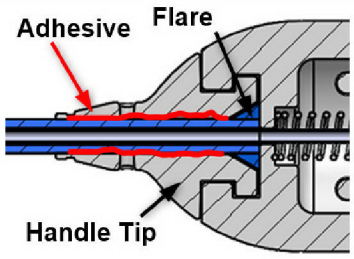
Performance testing for AcQCross™ Qx and the predicate device, the AcQGuide Catheter Introducer Sets, were performed in accordance with the following standards.

- 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, AcQCross™ Qx as a standalone device is identical to that of the predicate device, the AcQGuide Catheter Introducer Sets(K193509).

Table 5.6 describes the differences between the AcQGuide Catheter Introducer Sets and AcQCross™ Qx.

Table 5.6: Summary of differences between Predicate Device (K193509) and AcQCross™ Qx, Subject Device					
	AcQGuide Catheter Introducer Sets (K193509)		**AcQCross™ Qx Subject Device**		**Analysis of Differences**
Dilator shaft effective length	**Model**	**Length:**	**Model**	**Length**	Minor differences in dimensions do not potentially impact safety and effectiveness.
	AcQGuide Mini(50cm)	61.2cm± 2.0cm			
	AcQGuide Mini(65cm)	74.5cm± 2.0cm	900302	67.7cm ± 2.0cm	
	AcQGuide Flex(50cm)	75.9cm ± 2.0cm	900300, 900304	83.5cm ± 2.0cm	
	AcQGuide Flex(65cm)	89 cm ± 2.0cm	900301. 900303	93.4cm ± 2.0cm	
Dilator outer diameter (in.)	0.109"±.001"		**Model**	**Diameter**	Minor differences in dimensions do not potentially impact safety and effectiveness.
			900300, 900301, 900302	0.111" ± .001"	
			900303	0.114" ± .001"	
			900304	0.154" ± .001"	
Dilator distal tip outer diameter	.056"		.056" +.003/-.004		Minor differences in dimension does not potentially impact safety and effectiveness.
Handle lock feature	Handle tip compatible with AcQGuide Mini and Flex. 		Handle tip modified to be compatible with each compatible sheath.  FlexCath Agilis, Swartz Vizigo		Minor differences in tip do not potentially impact safety and effectiveness.
Dilator to handle bond	Flared dilator and mechanical lock, which sit into handle to prevent axial movement. Adhesive is applied to the interface between the handle tip and the dilator to prevent rotation.		Mechanical lock is removed, and new handle tip component with a chamfered end to fully encapsulate the proximal end of the dilator (including the flare) against the handle halves, preventing axial movement. Adhesive is applied between the handle tip and dilator to prevent rotation.		Minor modification to bond do not potentially impact safety and effectiveness.

			
Backer card	Modified to accommodate longer device models by relocating AcQCross™ securing feature 1.25” to 0.5” from the edge.		Packaging is otherwise identical. No change to backer card materials, thickness, or overall footprint. Minor modification does not potentially impact safety and effectiveness.
Colorant; non-patient contacting component	ABS Cornflower Colorant (Pantone 284C) ABS Dove Gray Colorant (Pantone 428C)	Lustran 348 ABS, Cool Grey PMS 3C Lustran, 348-012002, Orange PMS 144C	Modified colorant does not potentially impact safety and effectiveness.
Material change to spring; non-patient contacting component	Steel music wire	304 stainless steel	Minor change to material does not potentially impact safety and effectiveness.
Change to adhesive; indirect and non-patient contacting components	Loctite 401 & 411 (Base material: Ethyl Cyanoacrylate, Acrylic UV Curable)	Loctite 4060 (Base material: Ethyl Cyanoacrylate) Loctite 4311 (Base material: Acrylic UV Curable)	No change to base materials; minor change to adhesive formulation does not potentially impact safety and effectiveness.
Formulation of shaft material	40% LDPE, 40% HDPE, 20% BaSO4	70% HDPE, 30% BaSO4	Modified formulation does not potentially impact safety and effectiveness.
French size	8.5F	8.5F, 12F	French size determined by compatible sheath. Differences in dimension do not potentially impact safety and effectiveness.
Shaft Supplier	MET, Biomerics	MET, Biomerics, Apollo	Shaft supplier supplies identical components. Difference in supplier does not potentially impact safety and effectiveness.

AcQCross™ Qx and the AcQGuide Catheter Introducer Sets are otherwise identical in terms of materials, dimensions, packaging, shelf-life and sterilization. Therefore, performance testing has been leveraged from the AcQGuide Catheter Introducer Sets for the subject device. The following performance testing was conducted in support of the substantial equivalence determination.

5.4.1 Biocompatibility

Biocompatibility testing was performed on 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. Testing was performed on AcQCross™ Qx as packaged with the AcQGuide Catheter Introducer Sets, which is identified in this submission as the predicate device. Biocompatibility testing for the AcQGuide Catheter Introducer Sets(K193509) was submitted with the predicate device, Flextra™ Steerable Introducer (K170373) and Guider™ Catheter Introducer (K171081), with Lancer™ Integrated Dilator/Transseptal Needle. The previously submitted biocompatibility testing in K170373 and K171081 has been leveraged for the subject device. Additional cytotoxicity and hemolysis testing was performed as a result of a new shaft supplier. The results demonstrate that AcQCross™ Qx meets the requirements of ISO 10993-1 and is biocompatible.

5.4.2 Sterilization

Sterilization validation was performed on AcQCross™ Qx in accordance with 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, the AcQGuide Catheter Introducer Sets, to meet a sterility assurance level (SAL) of 10^{-6}. Testing was performed on AcQCross™ Qx as packaged with the AcQGuide Catheter Introducer Sets. The previously submitted sterilization validation of K170373 and K171081 has been leveraged for the subject device. The backer card was modified to accommodate the longer device models (900301, 900303), by relocating the AcQCross™ securing feature 1.25” to 0.5” from the edge. Otherwise, packaging for AcQCross™ Qx as a standalone device is identical to that of the AcQGuide Catheter Introducer Sets, with the exclusion of the introducer. This minor change was adopted into the existing process by Acutus Medical, Inc. 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 previously submitted EMC and Electrical Safety testing of K170373 and K171081, and of the predicate device (K193509) 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

Design verification and validation was performed on AcQCross™ Qx as packaged with the AcQGuide Catheter Introducer Sets, identified in this submission as the predicate device. Where appropriate, the previously submitted performance testing of K170373 and K171081, and of the predicate device (K193509) has been leveraged for the subject device. Acutus Medical, Inc. performed additional performance testing to the modified, standalone AcQCross™ Qx in support of substantial equivalence with the predicate device. The following testing was performed for the standalone AcQCross™ Qx:

- Curve retention
- Pushability
- Needle Actuation
- Electrical Continuity
- Shaft to handle tensile

Performance testing was also performed on AcQCross™ Qx with the various compatible sheaths to demonstrate that AcQCross™ performs as intended, and the addition of compatible sheath configurations do not potentially impact the safety or effectiveness of the device as compared to the predicate device. The following testing was performed:

- Needle Actuation
- Visual inspection
- Aspiration/Flushing
- Electrical Continuity

5.5 Conclusions

AcQCross™ Qx is a standalone version of a device that is currently cleared as a component of an introducer sheath system. AcQCross™ 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 tests demonstrated that the device is as safe and effective as the predicate device.