January 17, 2020

Acutus Medical, Inc.
℅ Prithul Bom
Official Correspondent
Regulatory Technology Services LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K193509
Trade/Device Name: AcQGuide® FLEX and AcQGuide® MINI Introducers with AcQCross™ Qx dilator/transseptal needle
Regulation Number: 21 CFR 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: December 16, 2019
Received: December 18, 2019

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,

for Nicole G. Ibrahim, Ph.D.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193509

Device Name
AcQGuide® Catheter Introducer Sets:
AcQGuide® FLEX and AcQGuide® MINI Introducers with AcQCross™ Qx dilator/transseptal needle

Indications for Use *(Describe)*
The AcQGuide® Catheter Introducer Sets are indicated for introducing various cardiovascular catheters into the heart, including the left side of the heart through the interatrial septum.

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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5.0 510(K) SUMMARY

510(k) Number: K193509 or TBD [X]

Date Prepared: December 6, 2019

Table 1: Submitter Information

Manufacturer: Acutus Medical 2210 Faraday Ave, Suite 100 Carlsbad, CA 92008 US FDA ERN: 3012120746	Manufacturer's Contact Person: Greg Geissinger Director of Regulatory Affairs and Quality Assurance Phone: (442) 232-6128 Fax: (442) 232-6081 Email: Greg.Geissinger@acutus.com

Table 2: Device Information

Trade Name	AcQGuide® Catheter Introducer Sets: AcQGuide® FLEX and AcQGuide® MINI Introducers with AcQCross™ Qx dilator/transseptal needle
Common Name	Catheter Introducer Sets
Classification Name	Introducer, Catheter
Regulation	21 CFR 870.1340
Product Code	DYB
Regulatory Classification:	Class II
Device Panel:	Cardiovascular

The Acutus AcQGuide Catheter Introducer sets are substantially equivalent to the previously cleared predicate Flextra Steerable Introducer and Guider Catheter Introducer sets (**Table 3**). Neither of these have been subject to a design-related recall.

Table 3: Predicate Devices

Predicate Device	Manufacturer	FDA 510(k)
Flextra Steerable Introducer Set	Acutus Medical	K170373
Guider Catheter Introducer Set	Acutus Medical	K171081

In the same manner as the current ECG adapter cable is attached to the AcQCross Qx dilator/transseptal needle, a new electrosurgical (ES) adapter cable is provided in the AcQGuide Catheter Introducer sets. The ES adapter allows for the option to apply RF current from commercially marketed ES generators to facilitate the septal puncture. This is done in a similar manner as Baylis Medical's NRG Transseptal Needle (**Table 4**).

Table 4: Reference Device

Reference Device	Manufacturer	FDA 510(k)
NRG Transseptal Needle	Baylis Medical	K073326

5.1 Device Description

The AcQGuide Catheter Introducer Sets (**Figure 1** and **Figure 2**) contain either a steerable introducer (AcQGuide FLEX) or fixed curve introducer (AcQGuide MINI), an integrated vessel dilator/transseptal needle (AcQCross Qx), guidewire, and electrocardiogram (ECG) and electrosurgical (ES) adapter cables. The sets are designed to facilitate vascular access to the heart and then provide variable catheter positioning within the cardiac anatomy.

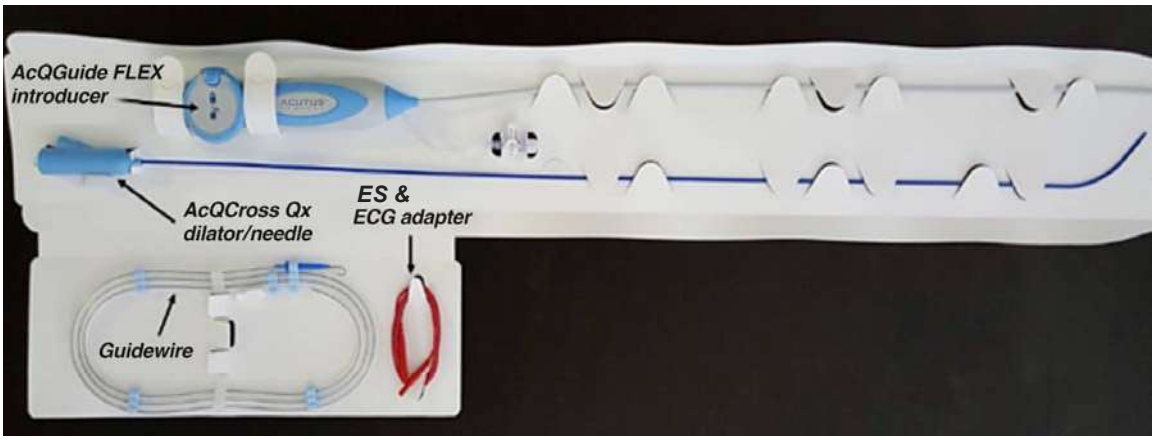

Figure 1: AcQGuide FLEX Catheter Introducer Set

Figure 2: AcQGuide MINI Catheter Introducer Set

The AcQGuide FLEX introducer (**Figure 3**) has an elongated shaft with central lumen capable of accepting the AcQCross Qx dilator/needle (**Figure 4**) as well as various cardiac catheters. The shaft has a proximal handle with a rotating actuator that allows the user to change the degree of curvature on the distal tip of the shaft (referred to as steerable tip, deflectable tip, or dynamic tip). Rotating the actuator can deflect the tip, in a planar fashion, +/- 180°. The handle is also fitted with a hemostasis valve to minimize blood loss during catheter introduction, and/or exchange, as well as a sideport with 3-way stopcock to allow blood aspiration, fluid infusion, and pressure monitoring. The introducer shaft features distal side holes to facilitate aspiration and prevent cavitation plus an embedded platinum radiopaque tip marker to facilitate fluoroscopic visualization.

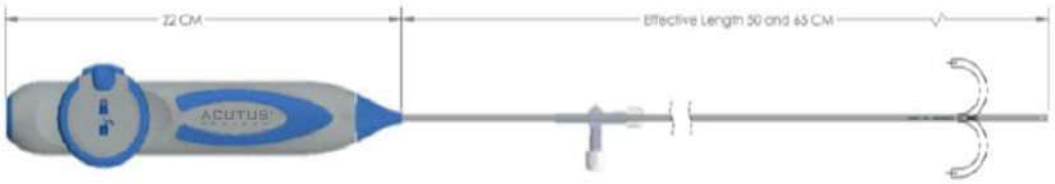

Figure 3: AcQGuide FLEX Introducer

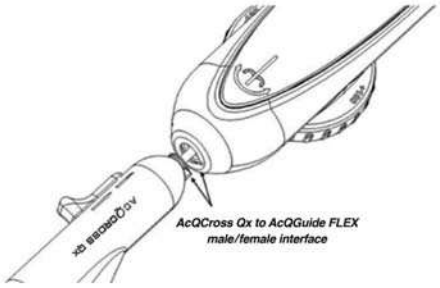

Figure 4: AcQGuide FLEX joined to AcQCross Qx

The AcQGuide MINI introducer (**Figure 5**) is an elongated shaft with central lumen capable of accepting the AcQCross Qx dilator/needle (**Figure 6**) as well as various cardiac catheters. The shaft is attached to a proximal handle that is fitted with a hemostasis valve to minimize blood loss during catheter introduction, and/or exchange, as well as a sideport with 3-way stopcock to allow blood aspiration, fluid infusion, and pressure monitoring. The introducer shaft features distal side holes to facilitate aspiration and prevent cavitation plus an embedded platinum radiopaque tip marker to facilitate fluoroscopic visualization. The distal end of the shaft has a preformed fixed-curve shape.

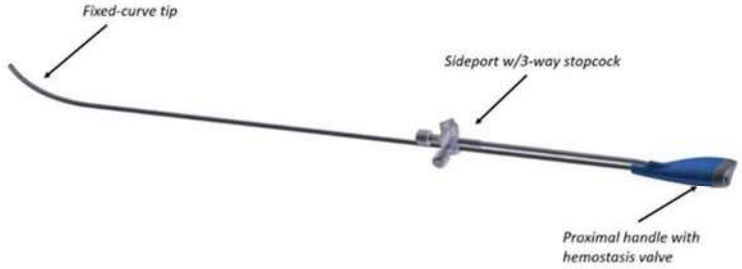

Figure 5: AcQGuide MINI Introducer

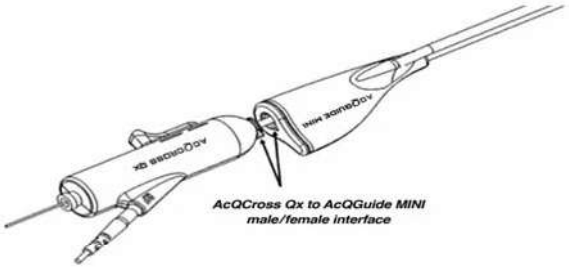

Figure 6: AcQGuide MINI joined to AcQCross Qx

The AcQCross Qx integrated dilator/transseptal needle (**Figure 7**) combines the vessel dilator and transseptal needle of the conventional devices into a single component. The AcQCross Qx consists of an elongated shaft with a tapered tip and central lumen to track over a guidewire in a similar fashion to conventional vessel dilators. The lumen of the AcQCross Qx is fitted with a hollow stainless steel transseptal needle and both the shaft and needle are connected to the same proximal handle. The needle lumen will accept guidewire sizes up to 0.032 inches in diameter. Inside the AcQCross Qx handle, the needle is affixed to a spring-tensioned actuator 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 a) allows monitoring an ECG from the needle while in the heart utilizing the ECG adapter cable, and/or b) allows application of radiofrequency (RF) current from an electrosurgical generator to facilitate the septal puncture utilizing the ES adapter cable.

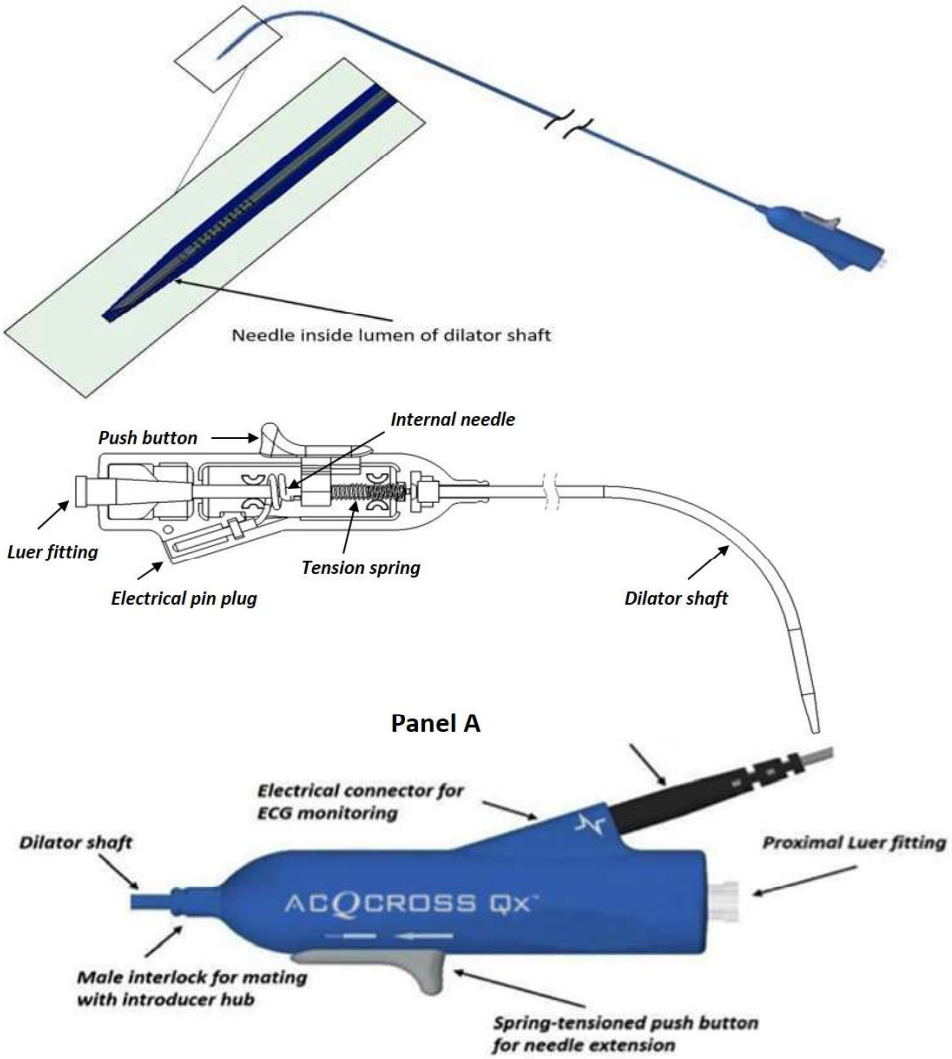

Figure 7: AcQCross Qx Dilator/Transseptal Needle

The guidewire included in the kit is manufactured by Lake Region Medical (K935170) and is supplied in a polypropylene retainer coil with a J-straightener and Luer fitting. The Luer fitting is compliant to ISO 594-1 and ISO 594-2. The ECG and ES adapter cables included are manufactured by Plastics One, are one (1) meter long, and are compliant with IEC 60601-1 and IEC 60601-2-2 safety standards.

5.2 Indications for Use

The AcQGuide Catheter Introducer Sets are indicated for introducing various cardiovascular catheters into the heart, including the left side of the heart through the interatrial septum.

5.3 Comparison of Technological Characteristics with the Predicate Device

The AcQGuide Introducer Sets are identical to the predicate Flextra Steerable Introducer (K170373) and Guider Catheter Introducer (K171081) sets except they are now provided with an ES adapter cable. The design of the introducer and dilator/transseptal needle devices remains unchanged. The inclusion of the ES adapter cable in the set allows the physician the option to use RF current as an adjunct during the transseptal puncture procedure. All other feature benefits remain unchanged.

The subject and predicate devices are based on the same technological elements of creating an atrial-septal defect (puncture) in the heart to allow for introduction of various cardiovascular catheters. The following technological difference exists between the subject and predicate devices:

- Use of a commercially available ES generator to apply RF current through the AcQCross Qx via the newly provided ES adapter cable. Although different from the predicate devices, this method is equivalent to that of the Reference Device – Baylis Medical NRG Transseptal Needle (K073326).

This difference provides convenience and efficiency over the predicate device and does not impact the intended use.

Due to supply issues, the hemostasis valve component of the AcQGuide Catheter Introducer Sets was changed from a polyisoprene valve to a silicone rubber valve. The silicone rubber valve is the same that is used in the Acutus AcQRef Introducer Sheath cleared via K192016 and originally via K171557 and whose biocompatibility has been assessed in those same filings. The performance of the new valve has been assessed to be substantially equivalent to the predicate devices through conduct of identical hemostasis leak testing specified in ISO 11070, *Sterile single-use intravascular introducers, dilators and guidewires*, Annex E.

5.4 Performance Data

The only changes made to the AcQGuide Catheter Introducer Sets include providing an ES adapter cable to optionally apply RF current from an ES generator to facilitate the septal puncture, updating the associated Instructions for Use (IFU), and changing the hemostasis valve from polyisoprene to silicone rubber. All other aspects of the devices remain unchanged. The testing performed on the AcQGuide Catheter Introducer Sets focused on the safety and performance of the ES assistance in generating the atrial-septal puncture.

The following performance data were provided in support of the substantial equivalence determination.

5.4.1 Biocompatibility

The AcQGuide Introducer Set devices are made of identical materials to the predicate devices with the exception of the modified hemostasis valve. The previously submitted biocompatibility testing of the predicate Flextra (K170373) and Guider (K171081) devices has been leveraged for the subject devices. The hemostasis valve in the new AcQGuide Catheter Introducer sets is of the identical material and similar design with that used in the Acutus AcQRef Introducer Sheath which has already been evaluated for biocompatibility by FDA via K192016. Therefore, no new biocompatibility testing was required for the subject devices.

5.4.2 Sterilization

The AcQGuide Introducer Set devices are subjected to the identical ethylene oxide (EO) sterilization process as the predicate devices to meet a sterility assurance level (SAL) of 10^{-6}. The addition of the ES adapter cable to the package has been adopted into the existing process per AAMI TIR28, *Product Adoption and Process Equivalence for Ethylene Oxide Sterilization*, and requires no further process validation. The shelf-life testing of the predicate devices has been leveraged for the subject devices and no additional shelf-life testing was required.

5.4.3 Electrical Safety and Electromagnetic Compatibility (EMC)

Electrical safety and EMC testing were conducted on the AcQGuide Introducer Set devices with the new ES adapter cable. The testing complies with the applicable sections of ES 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance,* and IEC 60601-1:2006+A12:2014, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*, IEC 60601-1-2:2014, *Medical electrical equipment – Part 1-2: General requirements for the basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests,* and IEC 60601-2-2:2017, *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*. This testing is consistent with that conducted by the reference device Baylis Medical's NRG Transseptal Needle (K073326).

5.4.4 Bench Testing

The AcQGuide Introducer Set devices were subject to ES Generator Compatibility testing including system connectivity, visual inspection for a) loose biological particulate, b) coring, and c) dilator damage. The packaging system is identical to the predicate and to provide added assurance the subject devices continue to meet packaging performance specifications, the devices underwent Distribution Cycle testing followed by visual inspection and electrical connectivity testing. The change in supply of the hemostasis valve was assessed to ensure the device's ability to maintain hemostasis was not affected. As such, the AcQGuide Catheter Introducer Sets with the new valve were tested to the same ISO 11070 Leak Test as the predicate devices.

All other performance testing has been leveraged from the predicate devices and no additional performance testing was required.

5.5 Conclusions

The AcQGuide Introducer Sets are of the identical materials and design of the predicate devices and have similar technical requirements. They perform as intended and present 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 the AcQGuide Introducer Sets perform as intended in the specified use conditions. The addition of the ES adapter cable for use in the optional RF method does not raise any new questions regarding safety or effectiveness of the device as compared to the reference device.

The AcQGuide Introducer Sets are substantially equivalent to the predicate Flextra Steerable Introducer set (K170373) and Guider Catheter Introducer set (K171081) devices.