May 14, 2021

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

Re: K211100
Trade/Device Name: AcQGuide MAX Steerable Sheath
Regulation Number: 21 CFR 870.1280
Regulation Name: Steerable catheter
Regulatory Class: Class II
Product Code: DRA
Dated: April 9, 2021
Received: April 13, 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,

Aneesh Deoras
Acting Assistant Director
Division of Cardiac
Electrophysiology, Diagnostics
and Monitoring Devices
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)*
K211100

Device Name
AcQGuide MAX Steerable Sheath

Indications for Use *(Describe)*
The AcQGuide MAX Steerable Sheath is intended for percutaneous catheter introduction into the vasculature and into the chambers of the heart.
The AcQGuide MAX deflection facilitates catheter positioning.

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

510(k) Number: K211100

Date Prepared: May 11, 2021

SUBMITTER INFORMATION [807.92(a)(1)]

Manufacturer:
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DEVICE INFORMATION [807.92(a)(2)]

Trade Name	AcQGuide® MAX Steerable Sheath
Common Name	Steerable Sheath
Classification Name	Catheter, Steerable
Regulation	21 CFR § 870.1280
Product Code	DRA
Regulatory Classification:	Class II
Device Panel:	Cardiovascular

The Acutus AcQGuide® MAX Steerable Sheath, Model 900200 is substantially equivalent to the predicate device, AcQGuide Steerable Sheath, Model 900002**.** Neither of these have been subject to a design-related recall.

PREDICATE DEVICE [807.92(a)(3)]

The predicate device to support substantial equivalence of the AcQGuide® MAX Steerable Sheath, Model 900200 is the Acutus Medical, Inc. AcQGuide Steerable Sheath, Model 900002, cleared under 510(k) K162925.

Predicate Device	Manufacturer	FDA 510(k)
AcQGuide Steerable Sheath	Acutus Medical, Inc.	K162925

DEVICE DESCRIPTION [807.92(a)(4)]

The AcQGuide® MAX Steerable Sheath, Model 900200 is a single use, percutaneous catheter introducer designed to provide additional maneuverability to interventional catheters that are advanced through the sheath and into the right or left chambers of the heart. The distal portion of the sheath is comprised of a composite structured single lumen shaft. At the proximal end, an ergonomic handle provides torque and active deflection, a hemostasis valve allows safe introduction of an interventional catheter, and a side port provides access for aspiration, fluid flushes and fluid/medication infusions.

The dilator is designed to introduce the Steerable Sheath into the vasculature and into chambers of the heart. The dilator has a smooth tapered tip and provides a smooth transition to the round edge of the non-traumatic tip of the sheath. The dilator is able to track over a 0.035” guidewire. The hub section is attached to the shaft. It is a standard female luer made of high-density polyethylene (HDPE) material.

Some of the key design attributes of the Steerable Sheath include:

- Deflectability
- Hemostasis
- Kink-resistance
- Visibility under fluoroscopy
- Easily flushed during the procedure
- Single-handed operation
- Biocompatible materials
- Sterile, single use
- Combined three-way stopcock

INDICATIONS FOR USE [807.92(a)(5)]

The AcQGuide MAX Steerable Sheath is intended for percutaneous catheter introduction into the vasculature and into the chambers of the heart.

The AcQGuide MAX deflection facilitates catheter positioning.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The subject device AcQGuide® MAX Steerable Sheath, Model 900200 has the same intended use and fundamental scientific technology as the predicate device. The purpose of this submission is to introduce the modified version of the Steerable Sheath and eventually replace the cleared AcQGuide® MAX Steerable Sheath, Model 900002 with the subject device. Table 1 provides a comparison of the predicate AcQGuide® MAX Steerable Sheath, Model 900002 classification against the subject device, comparison of the indications for use, and a comparison of the technological characteristics.

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TABLE 1: COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Table 1: COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE		
Characteristics	**Predicate Device** **AcQGuide® MAX Steerable Sheath, Model 900002** **(K162925)**	**Subject Device** **AcQGuide® MAX Steerable Sheath, Model 900200**
510(k) Number	K162925	TBD
Classification	21 CFR 870.1280	Identical
Product Code	DRA	Identical
Indications for Use	The AcQGuide is intended for percutaneous catheter introduction into the vasculature and into the chambers of the heart. The AcQGuide deflection facilitates catheter positioning.	Identical indications for use. Adding the product brand name "MAX" do not raise a new or different question of safety and effectiveness.
Device Identification		
Key Components	Employs single deflection curve with atraumatic tip. Sheath deflection facilitates accurate catheter positioning. Facilitates use with catheters up to 10.5 Fr in diameter. Hemostasis valve to prevent air incursion and minimizes blood loss. Flush port provides ability to administer saline flush throughout procedure. Usable length of up to 75 cm.	Identical key components with regards to sheath deflection, use with catheters up to 12 Fr in diameter, hemostasis valve and flush port. Usable length of up to 70 cm. The minor difference in sheath usable length do not raise a new or different question of safety and effectiveness in the subject device.
Sheath Size	Inner Diameter: 12.8 Fr (4.3 mm) Outer Diameter: 16 Fr (5.3 mm) Usable Length: 75 cm Total Length: 92 cm Radiopaque Marker: distal sections are visible when using standard or low-level fluoroscopy	Inner Diameter: 12.4 Fr (4.1 mm) Outer Diameter: 15.2 Fr (5.1 mm) Usable Length: 70 cm Total Length: 85 cm Identical radiopaque marker for visualization when using fluoroscopy. The minor differences in sheath size do not raise a new or different question of safety and effectiveness in the subject device.
Sheath Material	Shaft: Biocompatible copolymer (Pebax®) with stainless steel, platinum/10% Iridium, PTFE	Shaft: PTFE Liner for main lumen Pebax 4033 with 20-25% BaSO4, Pantone 422C, Pebax 5533 Pantone 419C, Pebax 3533 Pantone 422C, Pebax 6333 Pantone 422C, Pebax 7233 Pantone 422C.

Table 1: COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE		
Characteristics	**Predicate Device** **AcQGuide® MAX Steerable Sheath, Model 900002** **(K162925)**	**Subject Device** **AcQGuide® MAX Steerable Sheath, Model 900200**
		Both devices are constructed of biocompatible materials and PTFE Liner for main lumen (Pebax). The differences in color additives do not raise a new or different question of safety and effectiveness in the subject device.
Hemostasis Valve	Material: Shinetsu KEG-2000 50 A/B	Material: Silicone .080 NVR 50D (100578). The differences in hemostasis valve material do not raise a new or different question of safety and effectiveness in the subject device.
Radiopaque Marker	Total Length: .040” (1.0 mm)	Total Length: .039” (0.99 mm)
Dilator	Total Length: 95.5 cm Outer Diameter: 4.1 mm Inner Diameter: .039” (0.99 mm)	Total Length: 87.4 cm Outer Diameter: 4 mm Inner Diameter: .039” (0.99 mm) The differences in total length and outer diameter of the dilator do not raise a new or different question of safety and effectiveness in the subject device.
Steerable Sheath Total Weight	69.2 g	75 g. The difference in sheath total weight do not raise a new or different question of safety and effectiveness in the subject device.
Deflection and Reach	Maximum Deflection: 180 degrees Reach: 5.0 cm at 90 degrees	Identical
Compatibility	Guidewire compatibility: .035”	Identical
Method of Use	Percutaneous catheter introduction into the vasculature and into the chambers of the heart. The sheath deflection facilitates catheter positioning.	Same method of use.
Packaging	Pouch: Tyvek® 1073B Tyvek / 30655-O Film Pouch Card Tray: .035” HDPE, White Strap: .028” HDPE, White	Pouch: Tyvek® 1073B Tyvek / 30655-O Film Pouch Card Tray: .035” HDPE, White Strap: .028” HDPE, White

Table 1: COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE		
Characteristics	**Predicate Device** **AcQGuide® MAX Steerable Sheath, Model 900002** **(K162925)**	**Subject Device** **AcQGuide® MAX Steerable Sheath, Model 900200**
	EO Process Indicator Label: NAMSA radiation CPIs are non-odorous and non-hazardous to use Blank Label: Avery 8126 or equivalent 6 Pack Box: 200C Raft RSC Catheter Box (single): 200-E #W-BS	EO Process Indicator Label: NAMSA radiation CPIs are non-odorous and non-hazardous to use Blank Label: Avery 8126 or equivalent 6 Pack Box: 200C Raft RSC Catheter Box (single): 200-E #W-BS Identical packaging system.
Sterilization	Ethylene Oxide (EtO)	Identical
Shelf Life	18 months	12 months. The difference in shelf-life labeling do not raise a new or different question of safety and effectiveness in the subject device.

PERFORMANCE DATA [807.92(b)]

All necessary testing was conducted on the AcQGuide® MAX Steerable Sheath, Model 900200 to support a determination of substantial equivalence to the predicate device.

NONCLINICAL TESTING SUMMARY – BENCH [807.92(b)(1)]

The necessary bench testing was performed on the AcQGuide® MAX Steerable Sheath, Model 900200 in order to ensure that it conformed to the design specifications and to support a determination of substantial equivalence to the predicate device. The bench testing performed on the AcQGuide® MAX Steerable Sheath, Model 900200 consisted of the following:

- Packaging and shelf-life
- Sterilization
- Biocompatibility
- Design Verification and Validation studies, including:
    - Dimensional inspection of Sheath and Dilator
    - Visual inspection for any defects
    - Leak testing
    - Functional and compatibility testing
    - Mechanical testing
    - Handle torque testing
- Physician simulated use in an animal model

The collective results of the nonclinical testing demonstrate that the materials chosen, the manufacturing processes, and design of the AcQGuide® MAX Steerable Sheath, Model 900200 meets the specifications necessary for consistent performance during its intended use. In addition, the collective bench testing demonstrates that the AcQGuide® MAX Steerable Sheath, Model 900200 does not have any potential impact on the safety or effectiveness for percutaneous catheter introduction into the vasculature and into chambers of the heart, when compared to the predicate device.

The AcQGuide® MAX Steerable Sheath, Model 900200 was tested to verify that the device met its established performance specifications. This was done by utilizing dimensional testing to ensure that all components met the required dimensions per specifications, visual inspection to ensure that all components were free of defects, leak testing to ensure the packaging meets its specifications, functional and compatibility testing to ensure the functional and compatibility requirements are met, mechanical testing to ensure the components are able to withstand the expected forces, and handle torque testing to ensure it can withstand the expected torques.

CLINICAL TESTING SUMMARY [807.92(b)(2)]

This section is not applicable. No clinical testing is being submitted to support review of this 510(k) premarket notification.

BIOCOMPATIBILITY

The AcQGuide® MAX Steerable Sheath, Model 900200 is manufactured from materials similar to the predicate AcQGuide® MAX Steerable Sheath, Model 900002, and have passed all of the appropriate biocompatibility tests. Biocompatibility testing for the AcQGuide® MAX Steerable Sheath, Model 900200 was conducted in accordance with ISO 10993-1:2018 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process and the FDA Guidance Document titled, *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*" issued on September 4, 2020. The AcQGuide® MAX Steerable Sheath, Model 900200 has three components: a composite structured single lumen shaft, an ergonomic handle to provide torque and active deflection, and a hemostasis valve with side flush port. Each component was evaluated per the above standards and guidance documents to determine the appropriate biocompatibility testing. Per ISO 10993-1:2018, the AcQGuide® MAX Steerable Sheath is categorized as an external communicating device, which comes into contact with circulating blood for a limited (≤24 hours) contact duration.

STERILIZATION

Acutus Medical, Inc. conducted a technical review to compare the subject device AcQGuide® MAX Steerable Sheath, Model 900200 and the predicate device AcQGuide® MAX Steerable Sheath, Model 900002, to establish that the subject device can be adopted into the existing AcQGuide EtO processing cycle number ACU-537 at Steris Corporation. The predicate device AcQGuide® MAX Steerable Sheath, Model 900002 has been validated to an ethylene oxide sterilization process for a 10^{-6} sterility assurance level (SAL). The following aspects were used to perform the evaluation in accordance with ISO 11135:2014+A1:2019, packaging system, product design/materials, sterile barrier system, load configuration and bioburden resistance for the subject and predicate devices. Both the subject AcQGuide® MAX Steerable Sheath, Model 900200 and the predicate AcQGuide® MAX Steerable Sheath, Model 900002 product packaging systems use the same pouch, which consists of a sealed EtO compatible 1073B Tyvek pouch, 0.035" HDPE backer card and a secondary packaging (catheter shelf box). Additionally, both the subject and predicate devices are packaged in a corrugated cardboard shipper box, and uses the same packaging system, which contains (n=6) sheaths per shipper. The product packaging system does not adversely affect gas ingress or egress, nor does it pose a risk to product heating. The device is labeled and marketed as "Sterile" by Acutus Medical, Inc.

Shelf life study was performed to confirm acceptable product performance and ability to withstand sterilization. All materials identified were suitable for EtO sterilization and were not known to retain high EtO residual levels, or adversely impact the ability of EtO process

parameters to be met. In addition, Acutus Medical, Inc. performed material mediated pyrogenicity testing, to evaluate its potential to produce a pyrogenic response when tested in New Zealand white rabbits, per 21 CFR Part 58 Compliance Good Laboratory Practice for Nonclinical Laboratory Studies. The subject AcQGuide® MAX Steerable Sheath, Model 900200 is considered non-pyrogenic per the requirements of ISO 10993-11 guidelines.

ELECTRICAL SAFETY AND ELECTROMAGNETIC COMPATIBILITY (EMC)

This section is not applicable as the AcQGuide® MAX Steerable Sheath, Model 900200 is non powered and does not contain any electrical components.

CONCLUSIONS [807.92(b)(3)]

Extensive nonclinical testing has been performed on the AcQGuide® MAX Steerable Sheath, Model 900200 to evaluate the overall performance of the device. The subject device is substantially equivalent to the predicate device.