May 5, 2022

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

Re: K221044
Trade/Device Name: AcQGuide® VUE Steerable Sheath
Regulation Number: 21 CFR 870.1280
Regulation Name: Steerable catheter
Regulatory Class: Class II
Product Code: DRA
Dated: April 7, 2022
Received: April 8, 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,

Aneesh Deoras
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)*
K221044

Device Name
AcQGuide® VUE Steerable Sheath

Indications for Use *(Describe)*
The AcQGuide® VUE Steerable Sheath with electrodes is intended for percutaneous catheter introduction into the vasculature and into the chambers of the heart.
The AcQGuide® VUE deflection facilitates catheter positioning.
The electrodes help facilitate visualization of the sheath when used with a compatible localization system, such as the AcQMap System.

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: K221044

Date Prepared: May 4, 2022

SUBMITTER INFORMATION [807.92(a)(1)]

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

Trade Name	AcQGuide® VUE 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

PREDICATE DEVICE [807.92(a)(3)]

The predicate device to support substantial equivalence of the AcQGuide® VUE Steerable Sheath, Model 900201 is the Acutus Medical, Inc. AcQGuide® MAX Steerable Sheath, Model 900200, cleared under 510(k) K211100. This 510(k) is also citing the CARTO VIZIGO Bi-Directional Guiding Sheath cleared under K170997 as a reference device to support substantial equivalence for device containing electrodes.

Predicate Device	Manufacturer	FDA 510(k)	Product Code
AcQGuide® MAX Steerable Sheath	Acutus Medical, Inc.	K211100	DRA

Reference Device	Manufacturer	FDA 510(k)	Product Code
CARTO VIZIGO Bi-Directional Guiding Sheath	Biosense Webster	K170997	DYB

DEVICE DESCRIPTION [807.92(a)(4)]

The AcQGuide® VUE Steerable Sheath, Model 900201 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. There is a cable exiting from the handle of the sheath to provide connection for the distal electrodes. This cable terminates with four standard 2mm pins that are connected to the Auxiliary Interface Box or Auxiliary Catheter Cable of the AcQMap High Resolution Imaging and Mapping System, Model 900100 or 900000. The pin connections are assigned by the user for electrode identification (D1, 2, 3, 4) to the corresponding channel on the AcQMap System 900100. No designated order of pin connection is required. The AcQGuide® VUE Steerable Sheath includes a valve bypass tool as an optional accessory to facilitate the insertion of a loop or circular catheter.

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

The AcQGuide® VUE Steerable Sheath contents include the following:

- One (1) Acutus Medical AcQGuide® VUE Steerable Sheath
- One (1) Acutus Medical AcQGuide® Dilator
- One (1) Acutus Medical Valve Bypass Tool
- Product Information/Documentation (Instructions for Use)

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

The AcQGuide® VUE Steerable Sheath with electrodes is intended for percutaneous catheter introduction into the vasculature and into the chambers of the heart.

The AcQGuide® VUE deflection facilitates catheter positioning.

The electrodes help facilitate visualization of the sheath when used with a compatible localization system, such as the AcQMap System.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The subject device AcQGuide® VUE Steerable Sheath, Model 900201 has the same intended use and fundamental scientific technology as the predicate device. The predicate device, AcQGuide MAX Steerable Sheath, Model 900200(K211100), and the AcQGuide® VUE Steerable Sheath are identical in most technological characteristics, except for the addition of electrodes and related components used for sheath localization when used with a compatible mapping system. In addition, the AcQGuide® VUE when compared to the reference device provides electrical reference for visualization on the AcQMap System. The purpose of this submission is to introduce the AcQGuide® VUE Steerable Sheath. Table 1 below provides a comparison of the predicate AcQGuide® MAX Steerable Sheath and the reference device CARTO VIZIGO Bi-Directional Guiding Sheath, with regards to classification, comparison of the indications for use, and a comparison of the technological characteristics against the subject device.

TABLE 1: COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Table 1: COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE				
Characteristics	**Subject Device AcQGuide® VUE Steerable Sheath (K221044)**	**Predicate Device AcQGuide MAX Steerable Sheath K211100**	**Reference Device** CARTO VIZIGO Bi-Directional Guiding Sheath K170997	**Analysis of Differences**
Classification	21 CFR § 870.1280	21 CFR § 870.1280	21 CFR § 870.1340	The subject device and predicate device have the same classification number. The different classification number for the reference device does not raise a new or different question of safety and effectiveness.
Product Code	DRA	DRA	DYB	The subject device and predicate device have the same product code. The different product code for the reference device does not raise a new or different question of safety and effectiveness.
Indications for Use	The AcQGuide® VUE Steerable Sheath with electrodes is intended for percutaneous catheter introduction into the vasculature and into the chambers of the heart. The AcQGuide® VUE deflection facilitates catheter positioning. The electrodes help facilitate visualization of the sheath when used with a compatible localization system, such as the AcQMap System.	The AcQGuide MAX is intended for percutaneous catheter introduction into the vasculature and into the chambers of the heart. The AcQGuide MAX deflection facilitates catheter positioning.	The Biosense Webster CARTO VIZIGO™ 8.5F Bi-Directional Guiding Sheath is indicated for introducing various cardiovascular catheters into the heart, including the left side of the heart through the interatrial septum. The sheath curve can be visualized when used with compatible CARTO 3 EP Navigation Systems.	Similar indication for use language compared to the predicate. Proposed indications for use fall within the intended use for the predicate device. Similar indication for use compared to the reference device, related to utilizing electrodes to help visualization of the sheath. The differences in Indications for Use do not raise different questions of safety or effectiveness.

Table 1: COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE				
Characteristics	**Subject Device AcQGuide® VUE Steerable Sheath (K221044)**	**Predicate Device AcQGuide MAX Steerable Sheath K211100**	**Reference Device** CARTO VIZIGO Bi-Directional Guiding Sheath K170997	**Analysis of Differences**
Intended Use	Catheter Delivery System with sheath visualization when used with compatible mapping system	Catheter Delivery System	Catheter Delivery System with shaft visualization when used with a compatible CARTO 3EP navigation system.	Same intended use as the predicate device with regard to catheter delivery. Similar intended use as the reference device with respect to use of electrodes with catheter delivery system to assist with visualization when used with compatible mapping system. The differences in Intended Use do not raise different questions of safety or effectiveness.
Key Components	Employs single deflection curve with atraumatic tip. Sheath deflection facilitates accurate catheter positioning. Able to facilitate use with catheters up to 12 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 70 cm. Visibility of distal electrode under fluoroscopy. Electrodes that aide in visualization of sheath when used with the AcQMap System.	Employs single deflection curve with atraumatic tip. Sheath deflection facilitates accurate catheter positioning. Facilitates use with catheters up to 12 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 70 cm.	Bi-directional steerable sheath fitted with a hemostasis valve to minimize blood loss. Radiopaque tip marker to allow fluoroscopic visualization. 4 electrodes spaced along shaft to enable shaft visualization.	Identical key components as the predicate device with regards to usable length, French size compatibility, sheath deflection, hemostasis valve, and side flush port. Identical key components as the reference device with regards to sheath visibility of distal electrode under fluoroscopy, and electrodes that aide in visualization of sheath when used with a compatible mapping system.
Deflection and Reach	Maximum deflection: 180 degrees Reach: 5.0 cm at 90 degrees	Maximum deflection: 180 degrees Reach: 5.0 cm at 90 degrees	Maximum deflection: 180 degrees clockwise and counter clockwise Reach: Not available	Identical deflection mechanism and reach as the predicate device.

Table 1: COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE				
Characteristics	**Subject Device AcQGuide® VUE Steerable Sheath (K221044)**	**Predicate Device AcQGuide MAX Steerable Sheath K211100**	**Reference Device** CARTO VIZIGO Bi-Directional Guiding Sheath K170997	**Analysis of Differences**
Side Port for Flushing (Y/N)	Yes	Yes	Yes	Identical
Device Inner Diameter (ID) (French)	12.4 Fr (4.1 mm)	12.4 Fr (4.1 mm)	8.5Fr	Identical to predicate device.
Device Outer Diameter (OD)	15.2 Fr (5.1)mm	15.2 Fr (5.1)mm	11.5Fr	Identical to the predicate device.
Device Usable Length	70 cm	70 cm	71 cm	Identical to predicate device.
Device Overall Length	85cm	85cm	Not available	Identical to the predicate device
Device Materials	Sheath: 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 Hemostasis Valve: Silicone .80 NVR 50D (100578)	Sheath: 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 Hemostasis Valve: Silicone .80 NVR 50D (100578)	Not available	Identical to the predicate device.
Device Color Additives	Dupont 2020T 9002-88-4, Pebax	Dupont 2020T 9002-88-4, Pebax	Not available	Identical to the predicate device.
Radiopaque Marker	Total Length: .039" (0.99 mm). Distal sections are visible when using standard or low-level fluoroscopy	Total Length: .039" (0.99 mm). Distal sections are visible when using standard or low-level fluoroscopy	Radiopaque tip marker to allow fluoroscopic visualization.	Identical to predicate device.

Table 1: COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE				
Characteristics	**Subject Device AcQGuide® VUE Steerable Sheath (K221044)**	**Predicate Device AcQGuide MAX Steerable Sheath K211100**	**Reference Device** CARTO VIZIGO Bi-Directional Guiding Sheath K170997	**Analysis of Differences**
Guide wire compatibility	.035”	.035”	Not available	Identical to predicate device.
Dilator	Yes Overall Length: 90.02cm Usable Length: 87.4 cm Outer Diameter: 4 mm Inner Diameter: .039” (0.99 mm)	Yes Overall Length: 90.02cm Usable Length: 87.4 cm Outer Diameter: 4 mm Inner Diameter: .039” (0.99 mm)	Not available	Identical to predicate device.
Electrodes	Yes Platinum / Iridium	No	Yes Not available	Similar electrode material as the reference device. Minor differences in material do not raise different questions of safety or effectiveness.
Able to visualize sheath on Mapping System	Yes Acutus AcQMap System Model 900100 or 900000	No	Yes	Subject device is able to be visualized on the AcQMap System which is identical to the reference device used with compatible mapping system.
Sterilization Method	Ethylene Oxide (EtO)	Ethylene Oxide (EtO)	Ethylene Oxide (EtO)	Identical
Shelf Life	24 months	18 months	Not available	Minor differences in shelf life do not raise different questions of safety or effectiveness.
Biocompatible Blood, Body and Fluid Contacting Materials	Yes	Yes	Yes	Identical

PERFORMANCE DATA [807.92(b)]

All necessary testing was conducted on the AcQGuide® VUE Steerable Sheath, Model 900201 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® VUE Steerable Sheath, Model 900201 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® VUE Steerable Sheath, Model 900201 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® VUE Steerable Sheath, Model 900201 meets the specifications necessary for consistent performance during its intended use. In addition, the collective bench testing demonstrates that the AcQGuide® VUE Steerable Sheath, Model 900201 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® VUE Steerable Sheath, Model 900201 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® VUE Steerable Sheath, Model 900201 is manufactured from materials similar to the predicate AcQGuide® MAX Steerable Sheath, Model 900200, and has passed all of the appropriate biocompatibility tests. Biocompatibility testing for the AcQGuide® VUE Steerable Sheath, Model 900201 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® VUE Steerable Sheath, Model 900201 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® VUE Steerable Sheath is categorized as an external communicating device, which comes into contact with circulating blood for a limited (≤24 hours) contact duration.

STERILIZATION

AcQGuide® VUE is labeled and marketed as "Sterile" by Acutus Medical, Inc. AcQGuide® VUE is subjected to the identical ethylene oxide (EO) sterilization process as the predicate device, AcQGuide® MAX Steerable Sheath, Model 900200, to meet a sterility assurance level (SAL) of 10^{-6}. .Acutus Medical, Inc. conducted a technical review to establish that the subject device can be adopted into the existing AcQGuide EtO processing cycle number ACU-537 at Steris Corporation. The following aspects were used to perform the evaluation per AAMI TIR28:2009 and ISO 11135:2014: Packaging System Evaluation, Product Design/Materials, Barrier System, Load Configuration, and Bioburden Resistance.

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® VUE Steerable Sheath, Model 900201 is considered non-pyrogenic per the requirements of ISO 10993-11 guidelines.

ELECTRICAL SAFETY AND ELECTROMAGNETIC COMPATIBILITY (EMC)

For the purpose of this submission, the subject device AcQGuide® VUE Steerable Sheath requires an electrical safety evaluation. The AcQGuide® VUE has been assessed for electrical safety in accordance with IEC 60601-1, Medical electrical equipment Part 1: General requirements for basic safety and essential performance, and IEC 60601-1-2, Medical electrical equipment Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – requirements and tests. The AcQGuide® VUE Steerable Sheath is a CF Defibrillation proof applied part, used with the AcQMap System or any other 3D cardiac mapping system. The verification testing of the AcQGuide® VUE was constrained to the subset of Clauses 8.1 – 8.11 of IEC 60601-1. The completion of the following tests demonstrated that the AcQGuide® VUE is safe for its intended use:

- Defibrillation Proof Applied Parts (IEC 60601-1, Clause 8.5.5)
- Dielectric Voltage Withstand (IEC 60601-1, Clause 8.8.3)
- Sheath Leakage Current (IEC 60601-1, Clause 8.7)

The relevant test sections of IEC 60601-1-2 is as follows:

- Qualification testing of the AcQMap System with applied parts containing cables and Platinum-Iridium Electrodes.
- Qualification testing of the AcQMap System using general-purpose electrophysiology catheters to connect to the Auxiliary inputs.

The AcQGuide® VUE is built and constructed to be a general-purpose electrophysiology applied part. Therefore, using the AcQGuide® VUE as one of the applied parts does not invalidate or require retesting of the AcQMap Console. Additionally, retesting of the electromagnetic compatibility (EMC) is not required in order to release the AcQGuide® VUE catheter for use with the AcQMap System.

CONCLUSIONS [807.92(b)(3)]

Extensive nonclinical testing has been performed on the AcQGuide® VUE Steerable Sheath, Model 900201 to evaluate the overall performance of the device. The nonclinical tests demonstrated that the device is as safe and effective as the predicate device.