DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

April 6, 2017

Acutus Medical, Inc.
Brenda Clay
Regulatory Affairs Manager
2210 Faraday Ave
Suite 100
Carlsbad, California 92008

Re: K162925
Trade/Device Name: AcQGuide Steerable Sheath
Regulation Number: 21 CFR 870.1280
Regulation Name: Steerable Catheter
Regulatory Class: Class II
Product Code: DRA
Dated: March 3, 2017
Received: March 6, 2017

Dear Brenda Clay:

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. 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.

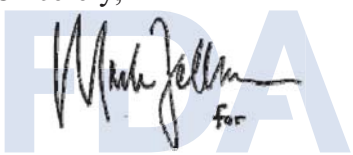
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162925

Device Name
AcQGuide Steerable Sheath

Indications for Use *(Describe)*
The AcQGuide is intended for percutaneous catheter introduction into the vasculature and into the chambers of the heart. The AcQGuide 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.

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510(k) Notification K162925

GENERAL INFORMATION [807.92(a)(1)]

Applicant:

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Date Prepared: April 3, 2017

DEVICE INFORMATION [807.92(a)(2)]

Trade Name:

AcQGuide™ Steerable Sheath

Generic/Common Name:

Steerable Catheter

Classification:

21 CFR 870.1280

Product Code:

DRA

PREDICATE DEVICE(S) [807.92(a)(3)]

The predicate device to support substantial equivalence of the AcQGuide Steerable Sheath is the Medtronic CryoCath LP Flexcath Advance® Steerable Sheath and Dilator cleared under K123591.

DEVICE DESCRIPTION [807.92(a)(4)]

The AcQGuide Steerable Sheath is a sterile, single use device consisting of a composite structured single lumen shaft, an ergonomic handle to provide torque and active deflection, and a hemostasis valve with side flush port, to allow safe introduction of a catheter while simultaneously permitting saline to be flushed via the main shaft. The AcQGuide Steerable Sheath is designed for maneuverability of standard electrophysiology catheters that are advanced through the sheath and into the right or left chambers of the heart. The sheath is compatible with diagnostic and therapeutic devices. The AcQGuide Steerable Sheath includes a dilator. The dilator is designed to introduce the Steerable Sheath into the vasculature and into chambers of the heart.

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

The AcQGuide is intended for percutaneous catheter introduction into the vasculature and into chambers of the heart. The AcQGuide deflection facilitates catheter positioning.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES [807.92(a)(6)]

Table 5.1: Substantial Equivalence Table – Regulatory Information

Feature	Proposed Device AcQGuide™ Steerable Sheath (K162925)	Predicate Device FlexCath Advance® Steerable Sheath K123591	Analysis of Differences
Classification	21 CFR § 870.1280	21 CFR § 870.1280	Same classification
Product Code	DRA	DRA	Same product code
Indications for Use	The AcQGuide Steerable Sheath is intended for percutaneous catheter introduction into the vasculature and into the chambers of the heart. The Sheath deflection facilitates catheter positioning.	The FlexCath Steerable Sheath is intended for percutaneous catheter introduction into the vasculature and into the chambers of the heart. The Sheath deflection facilitates catheter positioning.	Same intended use
Key Components	Employs single deflection curve with atraumatic tip. Sheath deflection facilitates accurate catheter positioning. Facilitates use with catheters up to 10.5F in diameter. Hemostasis valve to prevent air incursion and minimizes blood loss. Flush port provides ability to administer saline flush	Ergonomic handle with unidirectional deflection. Hemostasis valve allows for introduction, withdrawal, and exchanging of catheters and guide wires, while preventing air ingress and minimizing blood loss. Facilitates use with catheters up to	Similar design features. Minor differences do not raise different questions of safety or effectiveness.

Feature	Proposed Device AcQGuide™ Steerable Sheath (K162925)	Predicate Device FlexCath Advance® Steerable Sheath K123591	Analysis of Differences
	throughout procedure. Usable length of up to 75 cm.	10.5F in diameter. Usable length of up to 65 cm.	
Method of Use	Percutaneous catheter introduction into the vasculature and into the chambers of the heart. The sheath deflection facilitates catheter positioning.	Percutaneous catheter introduction into the vasculature and into the chambers of the heart. The sheath deflection facilitates catheter positioning.	Same method of use
Sheath Size	Inner diameter: 12.8Fr Outer Diameter: 16Fr Usable length: 75cm Total length: 92cm Radiopaque marker: distal sections are visible when using standard or low level fluoroscopy	Inner diameter: 12Fr Outer Diameter: 15Fr Usable length: 65cm Total length: 81cm Radiopaque marker: 5mm proximal to sheath tip	Products have similar inner and outer diameter and similar lengths. Both devices include radiopaque components for visualization. The minor differences do not raise different questions of safety or effectiveness.
Compatibility	Guidewire compatibility: .035”	Guidewire compatibility: .032” to .035”	The guidewire compatibility of AcQGuide falls within the range of the predicate.
Deflection and reach	Maximum deflection: 180 degrees (with catheter inserted) Reach: 5.0cm at 90 degrees	Maximum deflection: 135 degrees (with catheter inserted) Reach: 5.5cm at 90 degrees	Both devices allow deflection and have a similar reach.
Sheath Material	Shaft: Biocompatible copolymer (Pebax®) with stainless steel, platinum/10% Iridium, PTFE	Shaft: Biocompatible copolymer (Pebax®) with barium sulfate blend	Both devices are constructed of biocompatible materials
Dilator	Total length:95.5cm Outer diameter: 4.1mm	Total length: 87cm	The dilators of AcQGuide and the predicate are of similar length.

SUBSTANTIAL EQUIVALENCE

The proposed AcQGuide Steerable Sheath was compared to the predicate device with respect to product labeling, intended use, anatomical sites, patient population, performance testing, technological characteristics and safety characteristics. Based on this comparison, there were only minor differences in the technological characteristics between the devices which do not raise any different questions of safety or effectiveness. Thus, the AcQGuide is substantially equivalent to the predicate device.

PERFORMANCE DATA [807.92(B)]

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

[807.92(b)(1)] Nonclinical Testing Summary:

Extensive performance bench testing was conducted on the AcQGuide Steerable Sheath. This testing was performed in order to ensure that the AcQGuide Steerable Sheath performs as intended. The nonclinical testing included:

- 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 Steerable Sheath meet the established specifications necessary for consistent performance during its intended use. In addition, the collective bench testing demonstrates that the AcQGuide does not raise different questions of safety or effectiveness for percutaneous catheter introduction into the vasculature and into chambers of the heart when compared to the predicate devices.

[807.92(b)(2)] Clinical Testing Summary:

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

CONCLUSIONS [807.92(b)(3)]

Extensive nonclinical testing has been performed on the AcQGuide Steerable Sheath to evaluate the overall performance of the device. The collective results confirm that the AcQGuide Steerable Sheath is safe and effective, meets its specifications, is biocompatible, and exhibits the required mechanical and functional characteristics for its intended use.

SUMMARY

The AcQGuide Steerable Sheath is substantially equivalent to the predicate device