October 16, 2017

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

Re: K170819
Trade/Device Name: AcQMap 3D Imaging and Mapping Catheter
Regulation Number: 21 CFR 870.1220
Regulation Name: Electrode Recording Catheter or Electrode Recording Probe
Regulatory Class: Class II
Product Code: MTD, ITX
Dated: September 6, 2017
Received: September 7, 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 (DICE) 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 (DICE) 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,

for

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)*

K170819

Device Name

AcQMap 3D Imaging and Mapping Catheter

Indications for Use *(Describe)*

The AcQMap 3D Imaging and Mapping Catheter is intended to be used in the right and left atrial chambers to collect ultrasound data for visualizing the selected chamber and recording electrical impulses in patients with complex arrhythmias that may be difficult to identify using conventional mapping systems alone.

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) Notification K170819

GENERAL INFORMATION [807.92(a)(1)]

Applicant:

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Date Prepared: March 16, 2017

DEVICE INFORMATION [807.92(a)(2)]

Trade/Proprietary Name:
AcQMap® 3D Imaging and Mapping Catheter

Generic/Common Name:
Electrode Recording Catheter/Transducer Ultrasound

Classification:
II

Product Code:
MTD/ITX

510(k) SUMMARY

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

Predicate Device
Constellation Multiple Electrode Recording and Pacing Catheter ("Constellation Catheter") (K140733)

Reference Devices
EnSite Array Multi-Electrode Diagnostic Catheter ("EnSite Catheter") (K121006)
Ultra ICE Plus 9 MHz IntraCardiac Echo Catheter ("Ultra Ice Catheter") (K160173)

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

The AcQMap 3D Imaging and Mapping Catheter is intended to be used in the right and left atrial chambers to collect ultrasound data for visualizing the selected chamber and recording electrical impulses in patients with complex arrhythmias that may be difficult to identify using conventional mapping systems alone.

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

Characteristics	AcQMap 3D Imaging and Mapping Catheter	Constellation Multiple Electrode Recording and Pacing Catheter	Analysis
Regulatory			
510(k) Number	K170819	K140733	--
Classification/ Regulation Number/Regulation Name/Product Code	Class II/21 CFR § 870.1220/ Electrode recording catheter or electrode recording probe/MTD Class II/21 CFR § 892.1570/ Transducer Ultrasonic/ITX	Class II/21 CFR § 870.1220/ Electrode recording catheter or electrode recording probe/MTD	The additional product codes for the proposed device are required.
Indications for Use	The AcQMap 3D Imaging and Mapping Catheter is intended to be used in the right and left atrial chambers to collect ultrasound data for visualizing the selected chamber and recording electrical impulses in patients with complex arrhythmias that may be difficult to identify using conventional mapping systems alone.	For use in right atrial and left EP procedures to assist in the diagnosis of complex arrhythmias that may be difficult to identify using conventional mapping systems alone (i.e. linear mapping catheters). The Constellation Multiple Electrode Recording and Pacing Catheter System may also be used for delivery of	The intended use of the devices is the same.

510(k) SUMMARY

Characteristics	AcQMap 3D Imaging and Mapping Catheter	Constellation Multiple Electrode Recording and Pacing Catheter	Analysis
		externally generated pacing stimuli	

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

Characteristics	AcQMap 3D Imaging and Mapping Catheter	Constellation Multiple Electrode Recording and Pacing Catheter	Analysis
Physical Characteristics			
Configuration	Electrode/Transducer mounted on splines	Electrode Array in Basket	The differences in physical construction of the two devices do not raise different questions of safety or effectiveness than the predicate as demonstrated by the AcQMap performance testing.
Basket Diameter	25 mm	31, 38, 60 and 75mm	
Working Length	100 cm	90 cm – 130 cm (length)	
Number of Splines	6	8	
Heart Wall Contacting	No	Yes	
Flush Port	Yes	Unknown	
Technical Specifications – Electrical			
Voltage	Yes	Yes	Differences in electrical specifications do not raise different questions of safety or effectiveness than the predicate as demonstrated by the AcQMap performance testing.
Dipole Density	Yes	No	
Number of Electrodes	48	32 - 64	
Data Points/heart beat	2500	Unknown	
Power source	Electrical source from AcQMap System	Electrical source from standard EP mapping and recording Systems	
Technical Specifications – Ultrasound			
Mode	M-mode	N/A	The predicate device does not have ultrasound functionality. The reference device does have ultrasound functionality.
Number of transducers	48	N/A	
Phased Array Y/N	N	N/A	
Center Frequency	10 MHz	N/A	
Acoustic Output			
MI (Mechanical Index)	0.06	N/A	The predicate device does not have ultrasound functionality. The reference device does have ultrasound functionality.
ISTPA.3 (Derated Spatial-Peak Temporal-Average Intensity (milliwatts per square centimeter))	0.08 (mW/cm2)	N/A	
ISPPA.3 (Derated Spatial-Peak Pulse Average Intensity (watts per square centimeter))	1.03	N/A	
Accessories			

Characteristics	AcQMap 3D Imaging and Mapping Catheter	Constellation Multiple Electrode Recording and Pacing Catheter	Analysis
Compatible Sheath	For Use with Acutus Medical AcQGuide 12 F Steerable Sheath	9F	Any differences in accessory sizes do not raise different questions of safety or effectiveness.
Compatible Guidewire	0.032" (0.81 mm) diameter J-tip guidewire	Not to exceed 0.035" diameter J-tip guidewire	

SUBSTANTIAL EQUIVALENCE

The indications for use for the predicate device is substantially equivalent to the proposed indications for use for the AcQMap 3D Imaging and Mapping Catheter. Any differences in the technological characteristics between the devices do not raise different questions of safety or effectiveness. Thus, the AcQMap 3D Imaging and Mapping Catheter is substantially equivalent to the predicate device.

PERFORMANCE DATA [807.92(b)]

All necessary bench testing was conducted on the AcQMap 3D Imaging and Mapping Catheter to support a determination of substantial equivalence to the predicate device.

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

The nonclinical, bench testing included:

- Design Verification
  - Dimensional Inspection
  - Visual Inspection
  - Functional and Compatibility Testing
  - Mechanical Testing
  - Corrosion Testing
  - Electrode Coating Particulate Testing
  - Acoustic Output Testing
  - Accuracy Testing
- Design Validation
  - Usability Testing
  - Animal Testing
- Biocompatibility Testing

In addition, Acutus performed sterilization, shelf life and packaging validations. The collective results of the nonclinical testing demonstrate that the materials chosen, the manufacturing processes, and design of the AcQMap 3D Imaging and Mapping Catheter meet the established specifications necessary for consistent performance during its intended use. In addition, the collective bench testing demonstrates that the AcQMap 3D Imaging and

510(k) SUMMARY

Mapping Catheter does not raise different questions of safety or effectiveness for collecting data that enables the creation of 3D anatomic maps that display chamber-wide electrical activation when compared to the predicate device.

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

Although clinical testing is not required to demonstrate substantial equivalence to the predicate device for its intended use, Acutus performed a clinical study to demonstrate the safety and performance of the AcQMap High Resolution Imaging and Mapping System (AcQMap System) in gathering data to create right and/or left atrial dipole density activation maps in subjects with supraventricular tachycardia. The study entitled, "Dipole Density Right (and left) Atrial Mapping and Assessment of Therapy In Complex Supraventricular Tachycardia, (DDRAMATIC-SVT)" is a prospective, non-randomized, open-label study conducted at eight clinical sites outside the U.S. The results for 84 patients demonstrates that the AcQMap Catheter is safe and effective for its intended use.

CONCLUSIONS [807.92(b)(3)]

Extensive nonclinical performance testing was conducted on the AcQMap 3D Imaging and Mapping Catheter to evaluate the overall performance of the device. Acutus also performed validation testing including usability, accuracy and clinical testing to evaluate the performance of the AcQMap 3D Imaging and Mapping Catheter with the AcQMap System. The collective results demonstrate that the AcQMap 3D Imaging and Mapping Catheter is safe and effective for its intended use.

SUMMARY

The AcQMap 3D Imaging and Mapping Catheter is substantially equivalent to the predicate device.