October 16, 2017

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

Re: K170948
Trade/Device Name: AcQMap High Resolution Imaging and Mapping System
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK, IYO, ITX
Dated: September 15, 2017
Received: September 18, 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)*
K170948

Device Name
AcQMap® High Resolution Imaging and Mapping System

Indications for Use *(Describe)*
The AcQMap® High Resolution Imaging and Mapping System is intended for use in patients for whom electrophysiology procedures have been prescribed.

When used with the AcQMap Catheters, the AcQMap System is intended to be used to reconstruct the selected chamber from ultrasound data for purposes of visualizing the chamber anatomy and displaying electrical impulses as either dipole density-based or voltage-based maps of complex arrhythmias that may be difficult to identify using conventional mapping systems alone.

AND

When used with the specified Patient Electrodes, the AcQMap System is intended to display the position of AcQMap Catheters and conventional electrophysiology (EP) catheters in the heart.

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) Notification K170948

GENERAL INFORMATION [807.92(a)(1)]

Applicant:

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Date Prepared: March 29, 2017

DEVICE INFORMATION [807.92(a)(2)]

Trade Name:

AcQMap® High Resolution Imaging and Mapping System

Generic/Common Name:

Programable diagnostic computer and
Ultrasonic pulsed echo imaging system

Classification:

Class II/21 CFR § 870.1425 and
Class II/21 CFR § 892.1560

Product Code:

DQK, IYO, ITX

510(k) SUMMARY

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

- EnSite Velocity™ Cardiac Mapping System (K130594); and
- iLab™ Ultrasound Imaging System (K130243)

DEVICE DESCRIPTION [807.92(a)(4)]

The AcQMap System operates outside of the sterile field and consists of the AcQMap Console, the AcQMap Workstation, the AcQMap Patient Interface Unit, and the AcQMap Ablation Interface Unit.

The AcQMap High Resolution Imaging and Mapping System ("AcQMap System") is a diagnostic recording system. This computer-based system is intended for use in the Electrophysiology (EP) Lab, and it is capable of imaging, navigation and mapping of the atrial chambers of the heart.

The AcQMap System hardware consists of three functional subsystems:

- Ultrasound imaging,
- ECG and EGM recording; and
- Impedance based electrode Localization.

The AcQMap System is used in conjunction with the associated AcQMap 3D Imaging and Mapping Catheter. The AcQMap System provides:

- 3-D cardiac chamber reconstruction imaging,
- Three-dimensional position of the AcQMap Catheter and conventional electrophysiology catheters,
- Cardiac electrical activity as waveform traces,
- Remapping of the chamber at any time during the procedure; and
- Three-dimensional, dipole density maps overlaid on the cardiac chamber reconstruction to show chamber-wide electrical activation.

The AcQMap System is a diagnostic recording system consisting of ultrasound, electrical mapping components, a console, and a workstation. The AcQMap System is intended to create a surface reconstruction of the cardiac chamber as well as an electrical map of the substrate. The surface reconstruction and electrical map are then used by physicians to identify the source(s) of the arrhythmia.

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

The AcQMap System is intended for use in patients for whom electrophysiology procedures have been prescribed.

When used with the AcQMap Catheters, the AcQMap System is intended to be used to reconstruct the selected chamber from ultrasound data for purposes of visualizing the chamber anatomy and displaying electrical impulses as either dipole density-based or voltage-based maps of complex arrhythmias that may be difficult to identify using conventional mapping systems alone.

AND

When used with the specified Patient Electrodes, the AcQMap System is intended to display the position of AcQMap Catheters and conventional electrophysiology (EP) catheters in the heart.

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

Table 1 provides a comparison of the technological characteristics for the AcQMap System and the predicate devices.

Table 1: Comparison of Technological Characteristics with the Predicate Devices

Characteristics	AcQMap® High Resolution Imaging and Mapping System	EnSite™ Velocity™ Cardiac Mapping System	iLab™ Ultrasound Imaging System	Rationale for Substantial Equivalence
Regulatory				
510(k) Number	TBD	K130594	K130243	--
Classification/ Regulation Number/Regulation Name/Product Code	Class II/21 CFR § 870.1425/Programable diagnostic computer/DQK Class II/21 CFR § 892.1560/Ultrasonic pulsed echo imaging system/IYO, ITX	Class II/21 CFR § 870.1425/Programable diagnostic computer/DQK	Class II/21 CFR § 892.1560/Ultrasound pulsed echo imaging system/IYO, ITX	The additional product codes and regulation number for the proposed device are required.
Indications for Use	The AcQMap System is intended for use in patients for whom electrophysiology procedures have been prescribed. When used with the AcQMap Catheters, the AcQMap System is intended to be used to reconstruct the selected chamber from ultrasound data for purposes of visualizing the chamber anatomy and displaying electrical impulses as either dipole density-based or voltage-based maps of complex arrhythmias that may be difficult to identify using conventional mapping systems alone. AND When used with the specified Patient Electrodes, the AcQMap System is intended to display the position of AcQMap Catheters and conventional electrophysiology (EP) catheters in the heart.	The EnSite™ Velocity™ Cardiac Mapping System is a suggested diagnostic tool in patients for whom electrophysiology studies are indicated. *When used with the EnSite Array™ Catheter, the EnSite™ Velocity™ Cardiac Mapping System is intended to be used in the right atrium of patients with complex arrhythmias that may be difficult to identify using conventional mapping systems alone. OR *When used with the EnSite™ NavX™ Surface Electrode Kit, the EnSite™ Velocity™ Cardiac Mapping System is intended to display the position of conventional electrophysiology (EP) catheters in the heart.	The iLab™ Ultrasound Imaging System is intended for ultrasound examinations of intravascular pathology. Intravascular ultrasound is indicated in patients who are candidates for transluminal interventional procedures such as angioplasty and atherectomy.	All devices are intended for electrophysiology procedures. Both the AcQMap System and EnSite System are indicated for complex arrhythmias when used with their respective catheters. Both the AcQMap System and iLab System include the ultrasound performance capabilities in the indications for use statement. The semantic differences in the indications for use do not raise different questions of safety or effectiveness than the predicates as demonstrated by the AcQMap performance testing.

Table 1: Comparison of Technological Characteristics with the Predicate Devices (cont.)

Characteristics	AcQMap® High Resolution Imaging and Mapping System	EnSite™ Velocity™ Cardiac Mapping System	iLab™ Ultrasound Imaging System	Rationale for Substantial Equivalence
Patient Anatomy	Intracardiac Structures	Intracardiac Structures	Intravascular Anatomies	Based on the performance testing conducted, any difference in patient anatomy does not raise different questions of safety or effectiveness
Testing to Support Substantial Equivalence	• Software V/V • Electromagnetic and Electrical Safety • Verification Testing, • Accuracy Testing, • Animal Testing; and • Clinical Testing	• Bench testing; and • Animal testing	• Functional/performance testing • Interoperability testing; and • Electrical Safety testing	Complete performance testing conducted by Acutus demonstrates that the AcQMap System performs as intended and that there are no different questions of safety or effectiveness.
System Safety Standards	• IEC 60601-1: 2005 /A1:2012 • IEC 60601-2-37: 2007 • IEC 60601-1-2: 2007 /AC:2010 • IEC60601-1-6:2010	• IEC 60601-1, Issued 1988/12/01, • IEC 60601-1-1, Issued 2000/12/01, • IEC 60601-1-2, Issued 2004/11/01 • ANSI/AAMI ES1-1985 • UL 60601-1 • CAN/CSA C22.2 No. 601.1	Unknown	Same

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Table 1: Comparison of Technological Characteristics with the Predicate Devices (cont.)

Characteristics	AcQMap® High Resolution Imaging and Mapping System	EnSite™ Velocity™ Cardiac Mapping System	iLab™ Ultrasound Imaging System	Rationale for Substantial Equivalence
Physical Characteristics				
System Components	Console, Workstation, Workstation Cable Patient Interface Unit, Patient Interface Unit Cable, Ablation Interface Unit, Ablation Interface Unit Cable, Auxiliary Catheter Cable, Surface ECG Input Cable and Patient Electrode Kit.	Amplifier and Display Workstation (DWS) Amplifier includes Navlink, ArrayLink and CathLink Modules, SJM ECG Cable, Record Connect and GenConnect. DWS includes Workstation, Monitors, Isolation transformer, Video Extender, Media converter and fiber-optic cable	Unknown	Same
Visual/Mapping Characteristics	• 3-D cardiac chamber reconstructions imaging, • Three-dimensional position of the AcQMap Catheter and conventional electrophysiology catheters, • Cardiac electrical activity as waveform traces, • Remapping of the chamber at any time during the procedure; and • Three-dimensional, dipole density maps overlaid on the cardiac chamber reconstruction to show chamber-wide electrical activation.	• Three-dimensional position of the catheter • Display cardiac electrical activity as waveform traces; • Three-dimensional maps of the cardiac chamber	• Combination of imaging and soft tissue visualization. • Visualizes the catheter relative to the anatomical structure	The combination of three-dimensional imaging functionality and ultrasound functionality for display of dipole density maps does not raise different questions of safety or effectiveness as demonstrated through performance testing.
Visualization Device/Catheter	AcQMap Catheter (electrodes and transducers)	EnSite Array Catheter (electrode)	BSC Ultra ICE - Ultrasound Dx Catheter (transducer)	

Table 1: Comparison of Technological Characteristics with the Predicate Devices (cont.)

Characteristics	AcQMap® High Resolution Imaging and Mapping System	EnSite™ Velocity™ Cardiac Mapping System	iLab™ Ultrasound Imaging System	Rationale for Substantial Equivalence
Physical Characteristics - Console/Amplifier Comparison				
Dimensions	68 cm L x 48.3 cm W x 72.6 cm D	49 cm H x 46 cm W x 51 cm D	Unknown	Same
Weight Maximum	50 kg	31 kg	213 pounds (System weight)	
Power Requirement	110 – 240 V, 50/60 Hz	100, 110/120, 220/240 V ~50/60 Hz	Unknown	
Input Current	5A	450W maximum (4.5A)	Unknown	
Fuse protection	250 V, 6.3 A, two high breaking capacity fuses	250 V, 5 A VAC, two fuses	Unknown	

SUBSTANTIAL EQUIVALENCE

The indications for use for the predicate devices is substantially equivalent to the proposed indications for use for the AcQMap System. Any differences in the technological characteristics between the devices do not raise any different questions of safety or effectiveness. Thus, the AcQMap System is substantially equivalent to the predicate devices.

PERFORMANCE DATA [807.92(b)]

All necessary bench and clinical testing was conducted on the AcQMap System to support a determination of substantial equivalence to the predicate devices.

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

The necessary bench testing was performed on the AcQMap System to ensure that it conforms to the design specifications and to support a determination of substantial equivalence to the predicate device. The bench testing performed included the following:

- Transportation Testing
- AcQMap Verification Testing
- Software Verification and Validation
- System Accuracy Testing
- Electromagnetic Compatibility and Electrical Safety Testing
- AcQMap Catheter Validation Testing-Animal Study

The AcQMap System device was tested to verify that the device met the established performance specifications.

The collective results of the testing demonstrate that the design of the AcQMap System meets its established performance specifications necessary for performance during its intended use.

The collective results of the nonclinical testing demonstrate that the materials chosen, the manufacturing processes, and design of the AcQMap System meet the established specifications necessary for consistent performance during its intended use. In addition, the collective bench testing demonstrates that the AcQMap System 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 devices.

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

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 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 System is safe and effective for its intended use.

CONCLUSIONS [807.92(b)(3)]

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

SUMMARY

The AcQMap System is substantially equivalent to the predicate devices.