February 7, 2019

Acutus Medical, Inc.
Greg Geissinger
Director, Regulatory Affairs & Quality Assurance
2210 Faraday Ave, Suite 100
Carlsbad, California 92008

Re: K181577
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: January 2, 2019
Received: January 3, 2019

Dear Greg Geissinger:

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.

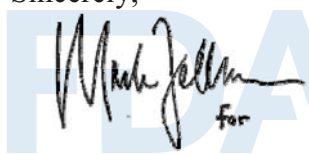
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181577

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) Notification K181577

GENERAL INFORMATION [807.92(a)(1)]

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Date Prepared: 02 January 2018

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

PREDICATE DEVICE [807.92(a)(3)]

AcQMap® High Resolution Imaging and Mapping System (K170948)

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 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-based 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 DEVICE [807.92(A)(6)]

This submission is seeking the clearance of the updated AcQMap System, which has the included software features, Anatomic Reference, Markers Enhancement, and Graphical User Interface Refresh.

Anatomic Reference allows the Anatomic Reference Channels to be used to subtract respiratory motion from all devices navigated by the system. With Marker Enhancement, markers can now be optionally "snapped" to the anatomy when the user-selected electrode is within 4mm of the reconstructed surface. Graphical User Interface Refresh is a functionality that was previously accessed through dropdown menus but can now be additionally accessed through readily available icons within the user interface.

Table 1 provides a comparison of the modified AcQMap System classification and indications for use against the predicate and reference devices. Table 2 provides a comparison of the technological characteristics for the modified AcQMap System against the predicate device.

Table 1: Comparison of Technological Characteristics with the Predicate Device

Characteristics	AcQMap® High Resolution Imaging and Mapping System	AcQMap® High Resolution Imaging and Mapping System	Rationale for Substantial Equivalence
Regulatory			
510(k) Number	K181577	K170948	
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/ Ultrasonic pulsed echo imaging system/ IYO, ITX	Identical
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 or voltage 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 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 or voltage 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.	Identical
Patient Anatomy	Intracardiac Structures	Intracardiac Structures	Identical
Testing to Support Substantial Equivalence	• Software V/V • Electromagnetic and Electrical Safety • Verification Testing, • Accuracy Testing, • Animal Testing; and Clinical Testing	• Software V/V • Electromagnetic and Electrical Safety • Verification Testing, • Accuracy Testing, • Animal Testing; and Clinical Testing	Identical
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: 2005 /A1:2012 • IEC 60601-2-37: 2007 • IEC 60601-1-2: 2007 /AC:2010 IEC60601-1-6:2010	Identical

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

Characteristics	AcQMap® High Resolution Imaging and Mapping System (K181577)	AcQMap® High Resolution Imaging and Mapping System (K170948)	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.	• 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.	Identical
Visual/Mapping Characteristics	• CT-like 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.	• CT-like 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.	Identical
Visualization Device/Catheter	AcQMap Catheter (electrodes and transducers)	AcQMap Catheter (electrodes and transducers)	Identical
Physical Characteristics - Console/Amplifier Comparison			
Dimensions	68 cm L x 48.3 cm W x 72.6 cm D	68 cm L x 48.3 cm W x 72.6 cm D	Identical
Weight Maximum	50 kg	50 kg	
Power Requirement	110 – 240 V, 50/60 Hz	110 – 240 V, 50/60 Hz	
Input Current	5A	5A	
Fuse protection	250 V, 6.3 A, two high breaking capacity fuses	250 V, 6.3 A, two high breaking capacity fuses	

SUBSTANTIAL EQUIVALENCE

The indications for use for the AcQMap High Resolution Imaging and Mapping System predicate device are identical to the proposed indications for use for the AcQMap High Resolution Imaging and Mapping System in this submission. 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 device.

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 device.

[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.

[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 demonstrate 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. 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 device, the previously cleared AcQMap System.