July 10, 2023

Acutus Medical Inc
Ryan Kenney
Director, Regulatory Affairs
2210 Faraday Ave, Suite 100
Carlsbad, California 92008

Re: K231091
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, ITX, IYO
Dated: April 17, 2023
Received: April 17, 2023

Dear Ryan Kenney:

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 S. Deoras -S

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)*
K231091

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 High Resolution Imaging and Mapping 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 charge 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 High Resolution Imaging and Mapping System is intended to display the position of AcQMap Catheters and conventional electrophysiology (EP) catheters in the heart.

OR

When used with conventional electrophysiology catheters, the AcQMap High Resolution Imaging and Mapping System provides information about the electrical activity of the heart and about catheter location during the procedure.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Applicant/Correspondent:	Applicant/Correspondent Contact:
Acutus Medical, Inc. 2210 Faraday Ave., Suite 100 Carlsbad, CA 92008 USA Phone: +1 (442) 232-6080 Fax: +1 (442) 232-6081	Ryan Kenney Director, Regulatory Affairs Email: ryan.kenney@acutus.com

Date Prepared:	July 6, 2023
Device Classification Name:	Computer, Diagnostic, Programmable
510(k) Number:	K231091
Device Name:	AcQMap High Resolution Imaging and Mapping System
Regulation Number:	870.1425
Classification Product Code:	DQK
Subsequent Product Codes:	ITX, IYO
Predicate Device:	AcQMap High Resolution Imaging and Mapping System (K222209)

Device Description:
The AcQMap High Resolution Imaging and Mapping System (hereafter referred to as the AcQMap System) operates outside of the sterile field and consists of the AcQMap Console, the AcQMap Workstation and the AcQMap Auxiliary Interface Box.

The 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 (3) functional subsystems:

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

The AcQMap System is used in conjunction with the AcQMap 3D Imaging and Mapping Catheter (hereafter referred to as the AcQMap Catheter). The AcQMap System provides:

- 3-D cardiac chamber reconstruction – Contact and non-contact (ultrasound),
- 3-D position of the AcQMap Catheter and conventional electrophysiology catheters,
- Cardiac electrical activity as waveform traces,
- Contact LAT and voltage amplitude maps
- Remapping of the chamber at any time during the procedure; and
- Dynamic, three-dimensional, charge density maps overlaid on the cardiac chamber reconstruction to show chamber-wide electrical activation.

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.

In addition, the AcQMap System allows physicians to perform traditional contact mapping activities, including establishing a coordinate system, localizing conventional electrophysiology catheters relative to one (1) another within the coordinate system, recording contact electrograms, and initiating a procedure without the AcQMap Catheter present. Based on the information captured in the contact electrograms, the physician may decide to treat an arrythmia without deploying the AcQMap Catheter.

There are no modifications to the hardware of the AcQMap System nor its accessories. The modifications to the AcQMap System are specific to the software, which include:

- The addition of the feature, Dynamic Referencing. Dynamic Referencing actively monitors impedance-based stability events like catheter drift or shift. Users will be offered guided notifications when shifts or drifts are automatically detected. Dynamic Referencing combines the capabilities of a Virtual Position Reference (VPR) and a Physical Position Reference (PPR), allowing them to be used together simultaneously. It is designed to be used instead of VPR or PPR alone. VPR and PPR remain available as options and
- Updated elements of the user interface to make it easier for the user to conduct a variety of actions within the software.

Indications for Use Statement:
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 charge 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.

OR

When used with conventional electrophysiology catheters, the AcQMap System provides information about the electrical activity of the heart and about catheter location during the procedure.

Comparison of Technological Characteristics:

Table 1: Comparison of Technological Characteristics		
Characteristics	AcQMap High Resolution Imaging and Mapping System Predicate Device (K222209)	AcQMap High Resolution Imaging and Mapping System Subject Device (K231091)
Regulation Number	870.1425	Same as K222209
Classification Product Code	DQK	Same as K222209
Subsequent Product Codes	ITX, IYO	Same as K222209
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 charge 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. OR When used with conventional electrophysiology catheters, the AcQMap System provides information about the electrical	Same as K222209

Table 1: Comparison of Technological Characteristics		
Characteristics	AcQMap High Resolution Imaging and Mapping System Predicate Device (K222209)	AcQMap High Resolution Imaging and Mapping System Subject Device (K231091)
	activity of the heart and about catheter location during the procedure.	
Patient Anatomy	• Intracardiac Structures	Same as K222209
Testing to Support Substantial Equivalence	• Software Verification/Validation • Electromagnetic and Electrical Safety • Verification Testing • Accuracy Testing • Animal Testing	Same as K222209
System Safety Standards	• IEC 60601-1:2005 /A1:2012 • IEC 60601-1-2:2014 • IEC 60601-2-25:2015 • IEC 60601-2-37:2015 • IEC 62366-1: 2015	Same as K222209
Physical Characteristics		
System Components	• Console • Workstation • Workstation Cable • Auxiliary Interface Box • ECG Input Cable • Ampere Ablation Catheter Adapter Cable • Ampere RF Generator Adapter Cable • ECG Output Cable • Ablation Reference Cable • Ablation Electrogram Cable • ECG w/Snaps Cable • ECG POST Cable • 2mm Pin Jumper Set • Patient Electrode Kit • Ampere Generator Adapter	Same as K222209

Table 1: Comparison of Technological Characteristics		
Characteristics	AcQMap High Resolution Imaging and Mapping System Predicate Device (K222209)	AcQMap High Resolution Imaging and Mapping System Subject Device (K231091)
	• SmartAblate Generator Adapter • Maestro Generator Adapter • Adapter Cable-Short – Ablation Adapter • Adapter Cable-Long – Ablation Adapter • SmartAblate Adapter Cable – Catheter • Maestro Adapter Cable – Catheter • Maestro Adapter Cable – Generator • Carto Force Adapter Cable • DiamondTemp Generator Adapter • DiamondTemp Adapter Cable – Generator	
Visual/Mapping Characteristics	• 3-D cardiac chamber reconstructions – Contact and non-contact (ultrasound) • 3-D position of the AcQMap Catheter and conventional electrophysiology catheters • Cardiac electrical activity as waveform traces • Contact LAT and voltage amplitude maps • Remapping of the chamber at any time during the procedure • Dynamic, 3-D, Charge Density maps overlaid on the cardiac chamber reconstruction to show chamber-wide electrical activation	Same as K222209
Visualization Device/Catheter	• AcQMap Catheter (electrodes & transducers) or • Conventional electrophysiology catheters	Same as K222209
Physical Characteristics – Console/Amplifier Comparison		
Dimensions	99 cm L x 58 cm W x 76 cm D	Same as K222209
Weight Maximum	80 kg	Same as K222209
Power Requirement	100-127 VAC, 50/60 Hz, 220-230 VAC, 50 Hz	Same as K222209
Input Current	4.6 A	Same as K222209

Table 1: Comparison of Technological Characteristics		
Characteristics	AcQMap High Resolution Imaging and Mapping System Predicate Device (K222209)	AcQMap High Resolution Imaging and Mapping System Subject Device (K231091)
Fuse Protection	250 V, 6.3A, two high breaking capacity fuses	Same as K222209
System Specifications		
Safety Information	IEC 60601-1, Class I, Type Defibrillator Protected CF, continuous operation, no sterilization, equipment not suitable for use in the presence of a flammable anesthetic mixture with air, oxygen or nitrous oxide	Same as K222209
Ingress Protection	The Console is rated IP20	Same as K222209
Functional and Performance Characteristics		
Ultrasound Output	Frequency: 10 MHz ± 400 kHz Maximum Voltage: 50 V p-p Maximum Power: 1 W Peak	Same as K222209
Ultrasound Performance	Single Operating Mode Thermal Index: < 1.0 Mechanical Index: < 1.0	Same as K222209
Localization Output	Frequency: Variable 15 kHz to 50 kHz Maximum Current: 1.2 mA	Same as K222209
ECG & EGM Input	Bandwidth: 0.05 Hz to 500 Hz Resolution: ± 1 uV Timing Accuracy: ± 1.6 microsecond	Same as K222209
Front Panel Connections		
AcQMap Catheter	Custom, Black, Defibrillator Protected Type CF	Same as K222209
ECG Input	12-pin, Latching, Red, Defibrillator Protected Type BF	Same as K222209
ECG Output	14-pin, Latching, Blue	Same as K222209
Auxiliary Interface Box	Custom, Green, Defibrillator Protected Type CF	Same as K222209
AcQRef Introducer Sheath or Electrical Reference Catheter	1, 2mm Female, Yellow, Defibrillator Protected Type CF	Same as K222209

Table 1: Comparison of Technological Characteristics		
Characteristics	AcQMap High Resolution Imaging and Mapping System Predicate Device (K222209)	AcQMap High Resolution Imaging and Mapping System Subject Device (K231091)
Localization Reference Electrodes	6, 2-pin, Square, Multi-color, Defibrillator Protected Type BF	Same as K222209
Patient Reference Electrode	1, 2-pin, Square, Blue, Defibrillator Protected Type BF	Same as K222209
Ablation Generator	10-pin, Latching, Grey	Same as K222209
Ablation Catheter	10-pin, Latching, Grey, Defibrillator Protected Type CF	Same as K222209
Ablation Reference	1, 2mm, Female, Black, Defibrillator Protected Type BF	Same as K222209
Ablation Electrogram Interface	1, 13-pin, Latching, White	Same as K222209

Substantial Equivalence:
The AcQMap System is intended to reconstruct the physiology and display the anatomic and electrical data in the same way. These modification are to improve the ease-of-use of some system capabilities. The updates to the mapping software includes:

- The addition of a corresponding mV scale in the color bar of charge density amplitude maps;
- User-initiated system checks for common connection errors such as cable disconnections and patch placement locations; and
- An improvement to the generation of the anatomic surface from ultrasound points.

These modification are to improve the ease-of-use of some system capabilities. There are no changes to the current mapping data. There are no differences between the subject device and the predicate(s) with respect to indications and intended use. Any differences in the technological characteristics between the devices do not raise any different questions of safety or effectiveness. Thus, the subject device is substantially equivalent to the predicate device.

Performance Data:
All necessary bench testing was conducted on the subject device to support a determination of substantial equivalence to the predicate device. The necessary clinical testing was completed for the original AcQMap System (K170948) and is incorporated by reference. No further clinical testing is required to support the subject device.

Non-Clinical Testing Summary:
The necessary bench testing was performed on the subject device to ensure that it conforms to the design specifications and to support a determination of substantial equivalence to the predicate device.

The following bench testing was repeated for the subject device:

- Software Verification and Validation

The balance of testing is incorporated by reference to the original AcQMap System (K170948), includes the following:

- Transportation Testing
- AcQMap High Resolution Imaging and Mapping Verification Testing
- System Accuracy Testing
- Electromagnetic Compatibility and Electrical Safety Testing
- AcQMap Catheter Validation Testing-Animal Study
- Accuracy Validation Testing Animal Study
- Clinical Simulation (Reliability)
- Map Accuracy Evaluation
- *In-vitro* Localization Accuracy Study

The subject device was tested to verify that it meets the established performance specifications. The collective results of the testing demonstrate that the design of the subject device meets its established performance specifications necessary for performance during its intended use.

The collective results of the non-clinical testing, either repeated for the subject device or incorporated by reference to the original AcQMap System (K170948), demonstrate that the materials chosen, the manufacturing processes, and design of the subject device meet the established specifications necessary for consistent performance during its intended use. In addition, the collective bench testing demonstrates that the subject device does not raise different questions of safety or effectiveness when compared to the predicate device.

Clinical Testing Summary:
As discussed above, no further clinical testing is required to support the subject device. The necessary clinical testing was completed for the original AcQMap System (K170948) and is incorporated by reference. That study, entitled, "Dipole Density Right (and Left) Atrial Mapping and Assessment of Therapy in Complex Supraventricular Tachycardia, (DDRAMATIC-SVT)" was a prospective, non-randomized, open-label study conducted at eight (8) clinical sites outside the U.S. The results for eighty-four (84) patients demonstrated that the AcQMap System is substantially equivalent to the predicate device.

Conclusion:
Extensive non-clinical performance testing, either repeated for the subject device or incorporated by reference to the original AcQMap System (K170948), was conducted to evaluate the overall performance of the device. The clinical validation of the original AcQMap System (K170948) is applicable to the subject device. Based on the performance testing and the technological characteristics, it can be concluded that the subject device is substantially equivalent to the predicate device.