December 1, 2020

Acutus Medical, Inc.
Serena Sanginthirath
Senior Regulatory Affairs Specialist
2210 Faraday Ave, Suite 100
Carlsbad, California 92008

Re: K201015
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: October 26, 2020
Received: October 27, 2020

Dear Serena Sanginthirath:

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,

Mark Fellman
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201015

Device Name
AcQMap® High Resolution Imaging and Mapping System, Model 900100

Indications for Use *(Describe)*

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.

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."

FORM FDA 3881 (7/17) Page 1 of 1 PSC Publishing Services (301) 443-6740 EF

510(k) SUMMARY

Date Prepared: April 20, 2020

GENERAL INFORMATION

Applicant:

Acutus Medical, Inc.
2210 Faraday Ave., Suite 100
Carlsbad, CA 92008, U.S.A
Phone: 1-442-232-6080
Fax: 1-442-232-6081

Contact Person:

Serena Sanginthirath
Senior Regulatory Affairs Specialist
Acutus Medical, Inc.
2210 Faraday Ave., Suite 100
Carlsbad, CA 92008, U.S.A
Phone: 1-442-232-6178
FAX: 1-442-232-6081
Email: Serena.Sanginthirath@acutus.com

DEVICE INFORMATION

Trade Name:

AcQMap® High Resolution Imaging and Mapping System, Model 900100

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(s):

DQK, IYO, ITX

PREDICATE DEVICE

AcQMap High Resolution Imaging and Mapping System, Model 900100 (K193013)

DEVICE DESCRIPTION

The AcQMap High Resolution Imaging and Mapping System, Model 900100 operates outside of the sterile field and consists of the AcQMap Console, the AcQMap Workstation and the AcQMap Auxiliary Interface Box.

The AcQMap High Resolution Imaging and Mapping System, Model 900100 ("AcQMap System Model, 900100") 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, Model 900100 is used in conjunction with the associated AcQMap 3D Imaging and Mapping Catheter (cleared under K170819). The AcQMap System provides:

- 3-D cardiac chamber reconstruction – Contact and non-contact (ultrasound),
- Three-dimensional 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, Model 900100 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.

Additionally, the AcQMap System allows physicians to perform traditional contact mapping activities, including establishing a coordinate system, localizing conventional electrophysiology catheters relative to one 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.

The AcQMap System is used with the AcQMap Patient Electrode Kit.

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 activity of the heart and about catheter location during the procedure.

COMPARISON TO PREDICATE DEVICES

The subject device has the same intended use and fundamental scientific technology as the predicate device. Therefore, the purpose of the submission is replacing the cleared Patient Electrode Kit with the AcQMap Patient Electrode Kit. Table 1 provides a comparison of the predicate AcQMap System classification against the subject device. Table 2 provides a comparison of the indications for use with the predicate device. Table 3 provides a comparison of the technological characteristics against the predicate device relating to the device accessory.

Table 1. Comparison of Classification with the Predicate Device

Characteristics	Predicate Device AcQMap® High Resolution Imaging and Mapping System, Model 900100 (K193013)	Subject Device AcQMap® High Resolution Imaging and Mapping System, Model 900100
510(k) Number	K193013	TBD
Classification/	Class II	Identical
Regulation Number/	21 CFR § 870.1425 21 CFR § 892.1560	
Regulation Name/	Programable diagnostic computer Ultrasonic pulsed echo imaging system	
Product Code	DQK, IYO, ITX	

Table 2. Comparison of Indications for Use with the Predicate Device		
Characteristics	Predicate Device	Subject Device
	AcQMap® High Resolution Imaging and Mapping System, Model 900100 (K193013)	AcQMap® High Resolution Imaging and Mapping System, Model 900100
510(k) Number	K193013	TBD
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 activity of the heart and about catheter location during the procedure.	Identical

Table 3: Comparison of Technological Characteristics Against the Predicate Device		
Characteristics	Predicate Device	Subject Device
	AcQMap® High Resolution Imaging and Mapping System, Model 900100 (K193013)	AcQMap® High Resolution Imaging and Mapping System, Model 900100
Patient Anatomy	Intracardiac Structures	Identical
Testing to Support Substantial Equivalence	• Software V/V • Electromagnetic and Electrical Safety • Verification Testing, • Accuracy Testing, and • Animal Testing	Identical
System Safety Standards	• IEC 60601-1:2005 /A1:2012 • IEC 60601-1-2:2014 • IEC 60601-1-6:2010/A1:2013 • IEC 60601-2-25:2015 • IEC 60601-2-37:2015	Identical
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 (800365-003)	All system components are identical, apart from the new Patient Electrode Kit (800605). Biocompatibility testing and performance testing on the new Patient Electrode Kit demonstrates that the AcQMap System and patient electrodes perform as intended. There are no different questions of safety or effectiveness.

Table 3: Comparison of Technological Characteristics Against the Predicate Device (Continued)		
Characteristics	Predicate Device	Subject Device
	AcQMap® High Resolution Imaging and Mapping System, Model 900100 (K193013)	AcQMap® High Resolution Imaging and Mapping System, Model 900100
Visual/Mapping Characteristics	• 3-D cardiac chamber reconstructions – Contact and non-contact (ultrasound); • Three-dimensional 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, three-dimensional, Charge Density maps overlaid on the cardiac chamber reconstruction to show chamber-wide electrical activation.	Identical
Visualization Device/Catheter	• AcQMap Catheter (electrodes & transducers) or • Conventional electrophysiology catheters	Identical
Physical Characteristics – Console/Amplifier Comparison		
Dimensions	99 cm L x 58 cm W x 76 cm D	Identical
Weight Maximum	80 kg	
Power Requirement	100-127 VAC, 50/60 Hz, 220-230 VAC, 50 Hz	
Input Current	4.6 A	
Fuse protection	250 V, 6.3A, two high breaking capacity fuses	

Table 3: Comparison of Technological Characteristics Against the Predicate Device (Continued)		
Characteristics	Predicate Device	Subject Device
	AcQMap® High Resolution Imaging and Mapping System, Model 900100 (K193013)	AcQMap® High Resolution Imaging and Mapping System, Model 900100
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	Identical
Ingress Protection	The Console is rated IP20	Identical
Functional and Performance Characteristics		
Ultrasound Output	Frequency: 10 MHz+/-400 kHz Maximum Voltage: 50V p-p Maximum Power: 1 W peak	Identical
Ultrasound Performance	Single operating mode Thermal Index less than 1.0 Mechanical Index less than 1.0	
Localization Output	Frequency: Variable 15 kHz to 50 kHz Maximum current: 1.2mA RMS	
ECG & EGM Input	Bandwidth: 0.05 Hz to 500 Hz Resolution: +/-1uV Timing Accuracy: +/-1.6 microsecond	

SUBSTANTIAL EQUIVALENCE

The indications for use of the subject device are identical to those of the predicate device. Any differences in the technological characteristics between the devices do not raise any different questions of safety or effectiveness. Thus, the modified AcQMap High Resolution Imaging and Mapping System, Model 900100, is substantially equivalent to the predicate device.

PERFORMANCE DATA

All necessary bench testing was conducted on the modified AcQMap System to support a determination of substantial equivalence to the predicate device.

NONCLINICAL TESTING SUMMARY

Design verification activities for functional testing were performed with their respective acceptance criteria to ensure that electrode patch modifications do not affect the safety or effectiveness of the device. All testing performed met the established performance specifications. Bench and animal testing were performed to verify the device met the pre-determined acceptance criteria. The following tests were performed.

- Performance Test
  - Gel adhesion
  - Electrode impedance
  - Wire insulation wall thickness
  - Lead wire pull strength
  - Lead wire flex life
- Biocompatibility Test
- Shelf-Life Test
- Usability Test
- Non-GLP Animal Test

The changes to the Patient Electrode Kit were evaluated through design verification and validation to show that the proposed AcQMap Patient Electrode Kit is acceptable for use and meets requirements.

The necessary bench testing was performed on the modified AcQMap High Resolution Imaging and Mapping System, Model 900100 to ensure that it conforms to the design specifications and to support a determination of substantial equivalence to the predicate device.

The collective results of the testing demonstrate that the design of the modified AcQMap High Resolution Imaging and Mapping System, Model 900100 meets its established performance specifications necessary for performance during its intended use.

The collective results of the nonclinical testing, either repeated for the modified device or incorporated by reference to the original AcQMap System 510(k) K193013, demonstrate that the materials chosen, the manufacturing processes, and design of the modified AcQMap High Resolution Imaging and Mapping System, Model 900100 meet the established specifications necessary for consistent performance during

its intended use. In addition, the collective bench testing demonstrates that the proposed device does not raise different questions of safety or effectiveness when compared to the predicate device.

CLINICAL TESTING SUMMARY

No further clinical testing is required to support the modified AcQMap High Resolution Imaging and Mapping System, Model 900100. 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 clinical sites outside the U.S. The results for 84 patients demonstrated that the AcQMap System is safe and effective for its intended use.

CONCLUSIONS

Nonclinical performance testing was conducted to the Patient Electrode Kit for the modified AcQMap System, to evaluate the overall performance of the device accessory. The clinical validation of the original AcQMap System (K170948) is applicable to the modified device. The collective results demonstrate that the modified AcQMap System, Model 900100 is safe and effective for its intended use. The subject AcQMap® High Resolution Imaging and Mapping System, Model 900100 is safe and effective for its intended use and is substantially equivalent to the predicate device.