September 6, 2019

Acutus Medical, Inc.
Karla Schaffner
Principal Regulatory Affairs Specialist
2210 Faraday Ave., Suite 100
Carlsbad, California 92008

Re: K191392
Trade/Device Name: AcQMap High Resolution Imaging and Mapping System, Model 900100
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK, IYO, ITX
Dated: August 12, 2019
Received: August 13, 2019

Dear Karla Schaffner:

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
DHT2A: Division of Cardiac
Electrophysiology, Diagnostics
and Monitoring Devices
OHT2: 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)*
K191392

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.

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510(K) NOTIFICATION K191392

GENERAL INFORMATION [807.92(a)(1)]

Date Prepared: 23 May 2019

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DEVICE INFORMATION [807.92(a)(2)]

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:

DQK, IYO, ITX

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

Predicate Device
AcQMap High Resolution Imaging and Mapping System, Model 900100 (K190131)

Reference Device
CARTO® 3 EP Navigation System, Version 6.0 And Accessories (K170600)

DEVICE DESCRIPTION [807.92(a)(4)]

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 modified 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.

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 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 WITH THE PREDICATE DEVICES [807.92(A)(6)]

Tables 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 Classification with the Predicate and Reference Devices

Characteristics	Subject Device	Predicate Device	Reference Device	Rationale for Substantial Equivalence
	AcQMap® High Resolution Imaging and Mapping System, Model 900100	AcQMap® High Resolution Imaging and Mapping System, Model 900100 (K190131)	CARTO® 3 EP Navigation System, Version 6.0 And Accessories	
510(k) Number	TBD	K190131	K170600	--
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	Class II/ 21 CFR § 870.1425/ Programable diagnostic computer/DQK	The subject device is identical to the predicate. The additional product code and regulation number for the subject and predicate device versus the reference device are required.

Table 2. Comparison of Indications for Use with the Predicate and Reference Devices

Characteristics	Subject Device	Predicate Device	Reference Device	Rationale for Substantial Equivalence
	AcQMap® High Resolution Imaging and Mapping System, Model 900100	AcQMap® High Resolution Imaging and Mapping System, Model 900100 (K190131)	CARTO® 3 EP Navigation System, Ver. 6.0 And Accessories	
510(k) Number	TBD	K190131	K170600	
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.	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 intended use of the CARTO® 3 System is catheter-based cardiac electrophysiological (EP) procedures. The CARTO® 3 System provides information about the electrical activity of the heart and about catheter location during the procedure. The system can be used on patients who are eligible for a conventional electrophysiological procedure. The system has no special contraindications.	All devices are intended for electrophysiology procedures. The additional paragraph in the modified AcQMap System indications for use is aligned with the indications for use of the reference device. The indications for use in the modified AcQMap System are otherwise identical to the predicate. The additional capability raises no new questions of safety or effectiveness as demonstrated by the AcQMap performance testing.

Table 3: Comparison of Technological Characteristics Against the Predicate Device			
Characteristics	Subject Device	Predicate Device	Rationale for Substantial Equivalence
	AcQMap® High Resolution Imaging and Mapping System, Model 900100	AcQMap® High Resolution Imaging and Mapping System, Model 900100 (K190131)	
Patient Anatomy	Intracardiac Structures	Intracardiac Structures	Identical
Testing to Support Substantial Equivalence	• Software V/V • Electromagnetic and Electrical Safety • Verification Testing, • Accuracy Testing, and • Animal Testing	• Software V/V • Electromagnetic and Electrical Safety • Verification Testing, • Accuracy Testing, • Animal Testing; and • Clinical 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 60601-1-2:2014 • IEC 60601-1-6:2010/A1:2013 • IEC 60601-2-25:2015 • IEC 60601-2-37:2015	• 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. There are no changes to hardware.
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	• 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	Identical

Table 3: Comparison of Technological Characteristics Against the Predicate Device (Continued)			
Characteristics	Subject Device	Predicate Device	Rationale for Substantial Equivalence
	AcQMap® High Resolution Imaging and Mapping System, Model 900100	AcQMap® High Resolution Imaging and Mapping System, Model 900100 (K190131)	
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.	• 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 • Dynamic, three-dimensional, Dipole Density maps overlaid on the cardiac chamber reconstruction to show chamber-wide electrical activation.	The additional capability to display cardiac electrical activity and catheter location without the AcQMap Catheter present does not raise different questions of safety or effectiveness as demonstrated through performance testing.
Visualization Device/Catheter	• AcQMap Catheter (electrodes & transducers) or • Conventional electrophysiology catheters	• AcQMap Catheter (electrodes & transducers)	
Physical Characteristics – Console/Amplifier Comparison			
Dimensions	99 cm L x 58 cm W x 76 cm D	99 cm L x 58 cm W x 76 cm D	Identical
Weight Maximum	80 kg	80 kg	
Power Requirement	100-127 VAC, 50/60 Hz, 220-230 VAC, 50 Hz	100-127 VAC, 50/60 Hz, 220-230 VAC, 50 Hz	
Input Current	4.6 A	4.6 A	
Fuse protection	250 V, 6.3A, two high breaking capacity fuses	250 V, 6.3A, two high breaking capacity fuses	

Table 3: Comparison of Technological Characteristics Against the Predicate Device (Continued)

Characteristics	Subject Device	Predicate Device	Rationale for Substantial Equivalence
	AcQMap® High Resolution Imaging and Mapping System, Model 900100	AcQMap® High Resolution Imaging and Mapping System, Model 900000 (K190131)	
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	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	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	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	Single operating mode Thermal Index less than 1.0 Mechanical Index less than 1.0	Identical
Localization Output	Frequency: Variable 15 kHz to 50 kHz Maximum current: 1.2mA RMS	Frequency: Variable 30 kHz to 60 kHz Maximum current: 2.2mA/cm2	Identical
ECG & EGM Input	Bandwidth: 0.05 Hz to 500 Hz Resolution: +/-1uV Timing Accuracy: +/-1.6 microsecond	Bandwidth: 0.1 Hz to 500 Hz Resolution: +/-10uV Timing Accuracy: +/-1.6 microsecond	Identical

Characteristics	Subject Device	Predicate Device	Rationale for Substantial Equivalence
	AcQMap® High Resolution Imaging and Mapping System, Model 900100	AcQMap® High Resolution Imaging and Mapping System, Model 900000 (K190131)	
Front Panel Connections			
AcQMap Catheter	Custom, black, Defibrillator Protected Type CF	Custom, black, Defibrillator Protected Type CF	Identical
ECG Input	12-pin, latching, red, Defibrillator Protected Type BF	12-pin, latching, red, Defibrillator Protected Type BF	Identical
ECG Output	14-pin, latching, blue	14-pin, latching, blue	Identical
Auxiliary Interface Box	Custom, green, Defibrillator Protected Type CF	Custom, green, Defibrillator Protected Type CF	Identical
AcQRef Introducer Sheath or Electrical Reference Catheter	1, 2mm female, yellow, Defibrillator Protected Type CF	1, 2mm female, yellow, Defibrillator Protected Type CF	Identical
Localization Reference Electrodes	6, 2-pin, square, multi-color, Defibrillator Protected Type BF	6, 2-pin, square, multi-color, Defibrillator Protected Type BF	Identical
Patient Reference Electrode	1, 2-pin, square, blue, Defibrillator Protected Type BF	1, 2-pin, square, blue, Defibrillator Protected Type BF	Identical
Ablation Generator	10-pin, latching, grey	10-pin, latching, grey	Identical
Ablation Catheter	10-pin, latching, grey, Defibrillator Protected Type CF	10-pin, latching, grey, Defibrillator Protected Type CF	Identical
Ablation Reference	1, 2mm, female, black, Defibrillator Protected Type BF	1, 2mm, female, black, Defibrillator Protected Type BF	Identical
Ablation Electrogram Interface	1, 13-pin, latching, white	1, 13-pin, latching, white	Identical

SUBSTANTIAL EQUIVALENCE

The indications for use of the subject device are substantially equivalent to those of the predicate and reference 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 [807.92(b)]

All necessary bench testing was conducted on the modified AcQMap System 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.

NONCLINICAL TESTING SUMMARY [807.92(b)(1)]

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 bench testing, either repeated for the modified device or incorporated by reference to the original AcQMap System 510(k), 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
- Contact Mapping Validation Testing Animal Study
- Accuracy Validation Testing Animal Study

The modified AcQMap High Resolution Imaging and Mapping System, Model 900100 was tested to verify that the device meets the established performance specifications. 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), 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 [807.92(b)(2)]

As discussed above, 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 [807.92(b)(3)]

Extensive nonclinical performance testing, either repeated for the modified device or incorporated by reference to the original AcQMap System 510(k), was conducted on the AcQMap High Resolution Imaging and Mapping System, Model 900100 to evaluate the overall performance of the device. 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.

SUMMARY

Based on the performance testing and the technological characteristics, it can be concluded that the modified 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.