April 2, 2019

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

Re: K190131
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 23, 2019
Received: January 28, 2019

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/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)*

K190131

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 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 K 190131

GENERAL INFORMATION [807.92(a)(1)]

Applicant:

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Date Prepared: January 23, 2019

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

510(k) SUMMARY

PREDICATE DEVICE [807.92(a)(3)]

AcQMap® High Resolution Imaging and Mapping System, Model 900000 (K170948)

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 Model, 900100 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 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, Model 900100 is a diagnostic recording system consisting of ultrasound, electrical mapping components, a console, workstation and an auxiliary interface box. 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.

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

510(k) SUMMARY

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)]

The indications for use for the AcQMap® High Resolution Imaging and Mapping System, Model 900100 are identical to the predicate device, AcQMap® High Resolution Imaging and Mapping System, Model 900000 (K170948).

The technological characteristics of the predicate device are very similar; with only a few minor differences.

Table 1 provides a comparison of the technological characteristics for the AcQMap System, Model 900100 with the predicate device.

510(k) SUMMARY

Table 1: Comparison of Technological Characteristics with 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 900000 (K170948)**	
510(k) Number	TBD	K170948	N/A
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	Same Classification/Regulation
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-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.	Same Indications for Use

510(k) SUMMARY

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

Characteristics	Subject Device AcQMap® High Resolution Imaging and Mapping System, Model 900100	Predicate Device AcQMap® High Resolution Imaging and Mapping System, Model 900000 (K170948)	Rationale for Substantial Equivalence
Manufacturer	Acutus Medical, Inc.	Acutus Medical, Inc.	Same Manufacturer
Patient Anatomy	Intracardiac Structures	Intracardiac Structures	Same Patient Anatomy
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, Model 900100 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 60601-2-37:2007	• IEC 60601-1: 2005 /A1:2012 • IEC 60601-2-37: 2007 • IEC 60601-1-2: 2007 /AC:2010 • IEC60601-1-6:2010	Same safety standards with compliance to current revisions. Improved safety by meeting additional relevant standard, IEC 60601-2-25:2011

510(k) SUMMARY

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

Characteristics	Subject Device AcQMap® High Resolution Imaging and Mapping System, Model 900100	Predicate Device AcQMap® High Resolution Imaging and Mapping System, Model 900000 (K170948)	Rationale for Substantial Equivalence
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 • Ablation Interface Unit • Ablation Interface Unit Cable • Auxiliary Catheter Cable • Surface ECG Input Cable • Patient Interface Unit, • Patient Interface Unit Cable • Ablation Generator • Catheter Adaptor Cables • Patient Electrode Kit	The subject device no longer includes the Patient Interface Unit and the Ablation Interface Unit. Based on the performance test conducted, any differences in system components, as well as the addition of the Auxiliary Interface Box, does not raise different questions of safety or effectiveness.
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.	• 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.	Same

510(k) SUMMARY

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

Characteristics	Subject Device AcQMap® High Resolution Imaging and Mapping System, Model 900100	Predicate Device AcQMap® High Resolution Imaging and Mapping System, Model 900000 (K170948)	Rationale for Substantial Equivalence
Visualization Device/Catheter	AcQMap Catheter (electrodes and transducers, K170819)	AcQMap Catheter (electrodes and transducers, K170819)	Same
Console Physical Characteristics			
Dimensions	99 cm L x 58 cm W x 76 cm D	68 cm L x 48.3 cm W x 72.6 cm D	Larger dimensions due to inclusion of locking caster base. The predicate device is built with non-locking casters. This slightly larger size accommodates improvements in clinical safety. The difference in dimensions does not raise safety or effectiveness as demonstrated through performance testing.
Weight Maximum	80 kg	50 kg	The difference in the maximum weight does not raise safety or effectiveness as demonstrated through performance testing.
Power Requirement	100-127 VAC, 50/60 Hz, 220-230 VAC, 50 Hz	110 – 240 V, 50/60 Hz	The difference in the power requirement does not raise safety or effectiveness, as the power in the subject device is lower and is demonstrated through performance testing.
Input Current	4.6 A	5A	The difference in the input current does not raise safety or effectiveness, as the input current in the subject device is lower and is demonstrated through performance testing.
Fuse protection	250 V, 6.3A, two high breaking capacity fuses	250 V, 6.3 A, two high breaking capacity fuses	Same

510(k) SUMMARY

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

Characteristics	Subject Device AcQMap® High Resolution Imaging and Mapping System, Model 900100	Predicate Device AcQMap® High Resolution Imaging and Mapping System, Model 900000 (K170948)	Rationale for Substantial Equivalence
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 CF, continuous operation, no sterilization, equipment not suitable for use in the presence of a flammable anesthetic mixture with air, oxygen or nitrous oxide	The addition of Defibrillation-Proof does not raise safety or effectiveness as demonstrated through performance testing.
Ingress Protection	The Console is rated IP20	The Console is rated IP20	Same
Functional and Performance Characteristics			
Ultrasound Output	Frequency: 10 MHz+/-400 kHz Maximum Voltage: 50V p-p Maximum Power: 1 W peak	Frequency: 10 MHz+/-10 kHz Maximum Voltage: 50V p-p Maximum Power: 1 W peak	The difference in frequency does not raise safety or effectiveness as demonstrated through performance testing. The ultrasound output is voltage limited in power (operating at the maximum voltage of the power supply). Additionally, widening the bandwidth from 10kHz to 400kHz has two primary advantages: 1.) It lowers the radiated emissions at 10Mhz and its harmonics (less interference radiated into other devices) 2.) It improves the spatial resolution of the reflected signal (improved accuracy)
Ultrasound Performance	Single operating mode Thermal Index less than 1.0 Mechanical Index less than 1.0	Single operating mode A Thermal Index less than 1.0 Mechanical Index less than 1.0	Same

510(k) SUMMARY

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

Characteristics	Subject Device AcQMap® High Resolution Imaging and Mapping System, Model 900100	Predicate Device AcQMap® High Resolution Imaging and Mapping System, Model 900000 (K170948)	Rationale for Substantial Equivalence
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	The reduction in localization frequency increases the input impedance of the localization system and improves localization accuracy. The difference in localization output does not raise safety or effectiveness as demonstrated through performance testing.
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	The change in bandwidth is to meet international standards. The change in resolution improves accuracy of dipole density maps. Changes does not raise safety or effectiveness as demonstrated through performance testing.
Front Panel Connections			
AcQMap Catheter	Custom, black, Defibrillator Protected Type CF	100-pin custom, Type CF	Defibrillation-Proof. The AcQMap Catheter connector is unchanged, system specifications have changed as discussed above, and does not raise different questions of safety or effectiveness as demonstrated through performance testing.
ECG Input	12-pin, latching, red, Defibrillator Protected Type BF	12-pin, latching, Type BF	Defibrillation-Proof. ECG Input connector is unchanged, system specifications have changed as discussed above, and does not raise different questions of safety or effectiveness as demonstrated through performance testing.
ECG Output	14-pin, latching, blue	--	The ECG output as a front panel connection does not raise safety or effectiveness as demonstrated through performance testing.

510(k) SUMMARY

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

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 (K170948)**	
Auxiliary Interface Box	Custom, green, Defibrillator Protected Type CF	--	Defibrillation-Proof. The AcQMap Auxiliary Interface Box provides connection to the auxiliary catheters (optional) used during the procedure. The AcQMap Auxiliary Interface Box also provides amplification of signals collected from auxiliary catheters and transfers these signals to the AcQMap Console for display. A universal bed rail clamp is provided for mounting. The addition of the AcQMap Auxiliary Interface Box does not raise different questions of safety or effectiveness as demonstrated through performance testing.
AcQRef Introducer Sheath or Electrical Reference Catheter	1, 2mm female, yellow, Defibrillator Protected Type CF	1, 2mm female, Type CF	Defibrillation-Proof. The AcQRef Introducer Sheath connector is unchanged, system specifications have changed as discussed above, and does not raise different questions of safety or effectiveness.
Localization Reference Electrodes	6, 2-pin, square, multi-color, Defibrillator Protected Type BF	6, 2-pin, square, Type BF	Defibrillation-Proof. The Localization Reference Electrodes connector are unchanged, system specifications have changed as discussed above, and does not raise different questions of safety or effectiveness.
Patient Reference Electrode	1, 2-pin, square, blue, Defibrillator Protected Type BF	1, 2-pin, square, Type BF	Defibrillation-Proof. The Patient Reference Electrode connector is unchanged, system specifications have changed as discussed above, and does not raise different questions of safety or effectiveness.

510(k) SUMMARY

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

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 (K170948)**	
Ablation Generator	10-pin, latching, grey	10-pin, male, Type CF	The Ablation Generator connector is unchanged, system specifications have changed as discussed above, and does not raise different questions of safety or effectiveness.
Ablation Catheter	10-pin, latching, grey, Defibrillator Protected Type CF	10-pin, female, Type CF	Defibrillation-Proof. The Ablation Catheter connector is unchanged, system specifications have changed as discussed above, and does not raise different questions of safety or effectiveness.
Ablation Reference	1, 2mm, female, black, Defibrillator Protected Type BF	--	Defibrillation-Proof. The ablation reference does not raise different questions of safety or effectiveness as demonstrated through performance testing.
Ablation Electrogram Interface	1, 13-pin, latching, white	--	This new cable added to the subject device does not raise different questions of safety or effectiveness as demonstrated through performance testing.

510(k) SUMMARY

SUBSTANTIAL EQUIVALENCE

The indication for use for the subject device, AcQMap® High Resolution Imaging and Mapping System, Model 900100, is substantially equivalent to the predicate. Any differences in the technological characteristics between the devices do not raise any different questions of safety or effectiveness. Thus, the 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 AcQMap® High Resolution Imaging and Mapping System, Model 900100 to support a determination of substantial equivalence to the predicate device. The necessary clinical study was completed for the original AcQMap System (K170948) and is incorporated by reference. No further clinical study is required to support the subject device.

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

The necessary bench testing was performed on the AcQMap 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 subject 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

The 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 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 proposed device or incorporated by reference to the original AcQMap System 510(k), demonstrate that the materials chosen, the manufacturing processes, and design of the 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 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 AcQMap® High Resolution Imaging and Mapping System, Model 900100 or incorporated by reference to the original AcQMap System 510(k), was conducted on the AcQMap System Model, 900100 to evaluate the overall performance of the device. The clinical validation of the original AcQMap System (K170948) is applicable to the subject device. The collective results demonstrate that the 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 AcQMap® High Resolution Imaging and Mapping System, Model 900100 is as safe and effective for its intended use and is substantially equivalent to the predicate device.