September 15, 2020

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

Re: K201341
Trade/Device Name: AcQMap 3D Imaging and Mapping Catheter, Model 900009
Regulation Number: 21 CFR 870.1220
Regulation Name: Electrode Recording Catheter Or Electrode Recording Probe
Regulatory Class: Class II
Product Code: MTD, ITX
Dated: August 5, 2020
Received: August 6, 2020

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
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)*
K201341

Device Name
AcQMap 3D Imaging and Mapping Catheter, Model 900009

Indications for Use *(Describe)*

The AcQMap 3D Imaging and Mapping Catheter is intended to be used in the right and left atrial chambers to collect ultrasound data for visualizing the selected chamber and recording electrical impulses in patients with complex arrhythmias that may be difficult to identify using conventional mapping systems alone.

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.

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# 510(K) NOTIFICATION K201341

## GENERAL INFORMATION [807.92(a)(1)]

**Date Prepared: 15 September 2020**

**Applicant:**

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## DEVICE INFORMATION [807.92(a)(2)]

**Trade Name:**

AcQMap® 3D Imaging and Mapping Catheter, Model 900009

**Generic/Common Name:**

Electrode Recording Catheter or Electrode Recording Probe/
Transducer Ultrasonic

**Classification:**

Class II / 21 CFR § 870.1220 and
Class II / 21 CFR § 892.1570

**Product Code(s):**

MTD/ITX

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

AcQMap 3D Imaging and Mapping Catheter (K170819)

## DEVICE DESCRIPTION [807.92(a)(4)]

The AcQMap 3D Imaging and Mapping Catheter ("AcQMap Catheter") is provided sterile and is a single-use, non-pyrogenic, invasive device that is inserted into the femoral vein and advanced through the venous circulatory system to the inferior vena cava and into the right and/or left atrium of the heart.

The AcQMap Catheter consists of a shaft with a lumen, an integral handle with a deployment mechanism and a flush port, and a connector, as shown in Figure 11.1. The AcQMap Catheter is intended to be used with the AcQMap High Resolution Imaging and Mapping System ("AcQMap System"). The AcQMap Catheter will provide ultrasound imaging and non-contact electrograms for Charge Density/Voltage heart chamber mapping. The AcQMap Catheter has six (6) splines at the distal end that support a configuration of 48 electrodes and 48 ultrasound transducers. The AcQMap Catheter is placed within the desired heart chamber and the distal end is deployed. There is no requirement for the electrodes or transducers to be in contact with the heart wall. The AcQMap Catheter is capable of over-the-wire delivery and contains a flexible distal segment that allows it to be directed via a steerable sheath to various locations and directions of interest within the heart. Refer to Figure 10.1 for images of the device.

The AcQMap Catheter, Model 900009 is sterilized by EO method, has a reusable interface cable, is compatible with a 0.035" guidewire, and has minor design changes to improve manufacturability.

## INDICATIONS FOR USE [807.92(a)(5)]

The AcQMap 3D Imaging and Mapping Catheter is intended to be used in the right and left atrial chambers to collect ultrasound data for visualizing the selected chamber and recording electrical impulses in patients with complex arrhythmias that may be difficult to identify using conventional mapping systems alone.

## DEVICE MODIFICATIONS

The following changes were introduced for the AcQMap Catheter Model 900009:

- Changed the distal basket material from nitinol to a molded plastic
- Updated the handle design from a rotating knob deployment to a sliding knob deployment
- Changed the distal tip design to a PEEK distal core and stainless steel distal ring
- Modified distal seal design
- Introduced a re-usable cable to reduce hospital waste
- Updated the design to accommodate a more common 0.035" guidewire
- Changed the sterilization method from e-beam radiation to EO
- Replaced coaxial wires with long flex circuits

**COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE [807.92(A)(6)]**

| Characteristics | SUBJECT<br>Modified AcQMap 3D Imaging & Mapping Catheter, Model 900009 | PREDICATE<br>AcQMap 3D Imaging & Mapping Catheter, Model 900003 | Rationale for Substantial Equivalence |
|---|---|---|---|
| **Regulatory** | | | |
| 510(k) Number | K201341 | K170819 | -- |
| Classification/ Regulation Number/ Regulation Name/ Product Code | Class II / 21 CFR §870.1220 / Electrode recording catheter or electrode recording probe / MTD<br>Class II / 21 CFR §892.1570 / Transducer Ultrasonic/ ITX | Class II / 21 CFR §870.1220 / Electrode recording catheter or electrode recording probe / MTD<br>Class II / 21 CFR §892.1570 / Transducer Ultrasonic/ ITX | Identical |
| Indications for Use | The AcQMap 3D Imaging and Mapping Catheter is intended to be used in the right and left atrial chambers to collect ultrasound data for visualizing the selected chamber and recording electrical impulses in patients with complex arrhythmias that may be difficult to identify using conventional mapping systems alone. | The AcQMap 3D Imaging and Mapping Catheter is intended to be used in the right and left atrial chambers to collect ultrasound data for visualizing the selected chamber and recording electrical impulses in patients with complex arrhythmias that may be difficult to identify using conventional mapping systems alone. | Identical |
| **Physical Characteristics** | | | |
| Configuration | Electrode/Transducer mounted on splines | Electrode/Transducer mounted on splines | Identical |
| Deployed Diameter | 25mm | 25mm | |
| Working Length | 100 cm | 100 cm | |
| Number of Spines | 6 | 6 | |
| Heart Wall Contacting | No | No | |
| Deflection Y/N | No | No | |
| Flush Port | Yes | Yes | |
| **Technical Specifications – Electrical** | | | |
| Voltage | Yes | Yes | Identical |
| Charge Density | Yes | Yes | |
| Number of Electrodes | 48 | 48 | |
| Data Points/heartbeat | 2500 | 2500 | |
| Power source | Electrical source from AcQMap System | Electrical source from AcQMap System | |
| **Technical Specifications – Ultrasound** | | | |
| Mode | M-mode | M-mode | Identical |
| Number of transducers | 48 | 48 | |
| Phased Array Y/N | N | N | |
| Center Frequency | 10 MHz | 10 MHz | |

| Characteristics | SUBJECT<br>Modified AcQMap 3D Imaging and Mapping Catheter, Model 900009 | PREDICATE<br>AcQMap 3D Imaging and Mapping Catheter, Model 900003 | Rationale for Substantial Equivalence |
|---|---|---|---|
| **Acoustic Output** | | | |
| MI (Mechanical Index) | 0.06 | 0.06 | Identical |
| ISTPA.3 (Derated Spatial-Peak Temporal-Average Intensity (milliwatts per square centimeter)) | 0.08 ($mW/cm^2$) | 0.08 ($mW/cm^2$) | |
| ISPPA.3 (Derated Spatial-Peak Pulse Average Intensity (watts per square centimeter)) | 1.03 | 1.03 | |
| **Accessories** | | | |
| Compatible Sheath | For Use with Acutus Medical AcQGuide 12 F Steerable Sheath (K162925) | For Use with Acutus Medical AcQGuide 12 F Steerable Sheath (K162925) | Identical |
| Compatible Guidewire | 0.035" (0.89 mm) diameter J-tip guidewire | 0.032" (0.81 mm) diameter J-tip guidewire | The difference in accessory size compatibility does not raise different questions of safety or effectiveness |

## 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 3D Imaging and Mapping Catheter, is substantially equivalent to the predicate AcQMap 3D Imaging and Mapping Catheter device.

## PERFORMANCE DATA [807.92(b)]

All necessary bench testing was conducted on the modified AcQMap 3D Imaging and Mapping Catheter to support a determination of substantial equivalence to the predicate device. The necessary clinical testing was completed for the original AcQMap Catheter (K170819) and is incorporated by reference. No further clinical testing is required to support the subject device.

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

The nonclinical, bench testing is repeated or included in this submission by reference. A full list of the non-clinical testing is provided below:

- Design Verification
  - Dimensional Inspection
  - Visual Inspection
  - Functional (electrical) and Compatibility Testing
  - Mechanical Testing (tensile testing)
  - Corrosion Testing
  - Electrode Coating Particulate Testing
  - Acoustic Output Testing
  - Accuracy Testing
- Design Validation
  - Usability Testing
  - Animal Testing
- Biocompatibility Testing including NAVI testing

In addition, Acutus performed sterilization, shelf life and packaging validations. The collective results of the nonclinical testing demonstrate that the materials chosen, the manufacturing processes, and design of the AcQMap 3D Imaging and Mapping Catheter meet the established specifications necessary for consistent performance during its intended use. In addition, the collective bench testing demonstrates that the AcQMap 3D Imaging and Mapping Catheter does not raise different questions of safety or effectiveness for collecting data that enables the creation of 3D anatomic maps that display chamber-wide electrical activation 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 3D Imaging and Mapping Catheter. The necessary clinical testing was completed for the original AcQMap 3D Imaging and Mapping Catheter (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 3D Imaging and Mapping Catheter 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 3D Imaging and Mapping Catheter 510(k), was conducted on the modified AcQMap 3D Imaging and Mapping Catheter to evaluate the overall performance of the device. The clinical validation of the original AcQMap 3D Imaging and Mapping Catheter (K170819) is applicable to the modified device. The collective results demonstrate that the modified AcQMap 3D Imaging and Mapping Catheter is safe and effective for its intended use, and further, is substantially equivalent to the predicate device