September 3, 2019

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

Re: K192106
Trade/Device Name: AcQRef Introducer Sheath
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: August 1, 2019
Received: August 5, 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/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)*
K192106

Device Name
AcQRef® Introducer Sheath

Indications for Use *(Describe)*
The Acutus Medical AcQRef Introducer Sheath is indicated for use in percutaneous procedures to facilitate venous access from the lower extremities for introduction of catheters and other devices, and may be used to sense intravenous signals.

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) SUMMARY

510(K) NOTIFICATION K192106

GENERAL INFORMATION [807.92(a)(1)]

Date Prepared: August 2, 2019

Applicant:

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DEVICE INFORMATION [807.92(a)(2)]

Trade Name:

AcQRef® Introducer Sheath

Generic/Common Name:

Catheter Introducer

Classification:

Class II, 21 CFR §870.1340

Product Code:

DYB

510(K) SUMMARY

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

AcQRef Introducer Sheath (K171557), manufactured by Acutus Medical, Inc.

DEVICE DESCRIPTION [807.92(a)(4)]

The Acutus Medical AcQRef Introducer Sheath is a sterile, single use, venous access device that consists of a straight shaft with lumen, hemostasis valve, flush port, electrode, and attached extension cable for electrode connectivity
The AcQRef Introducer Sheath consists of the following components:

- One (1) 7Fr Introducer Sheath with electrode and connection cable
- One (1) 7Fr Vessel Dilator
- One (1) Guidewire - .038 in, J-tip

The electrode is connected to the yellow cable and connector. The AcQRef Introducer Sheath is compatible for use with the AcQMap® High Resolution Imaging and Mapping System Models 900000, cleared under 510(k) K181577 and 900100, cleared under 510(k) K190131.

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

The Acutus Medical AcQRef Introducer Sheath is indicated for use in percutaneous procedures to facilitate venous access from the lower extremities for introduction of catheters and other devices, and may be used to sense intravenous signals.

510(K) SUMMARY

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

Substantial Equivalence Table			
Feature	**Subject Device** **AcQRef Introducer Sheath** **TBD**	**Predicate Device** **AcQRef Introducer Sheath** **(K171557)**	**Analysis of Differences**
Classification	21 CFR § 870.1340	21 CFR § 870.1340	Identical
Product Code	DYB	DYB	Identical
Indications for Use	The Acutus Medical AcQRef Introducer Sheath is indicated for use in percutaneous procedures to facilitate venous access from the lower extremities, for introduction of catheters and other devices, and may be used to sense intravenous signals.	The Acutus Medical AcQRef Introducer Sheath is indicated for use in percutaneous procedures to facilitate venous access from the lower extremities, for introduction of catheters and other devices, and may be used to sense intravenous signals.	Identical
Intended Use	Catheter delivery system including electrodes for intravenous signal sensing when used with compatible mapping system.	Catheter delivery system including electrodes for intravenous signal sensing when used with compatible mapping system.	Identical
Device Inner Diameter (ID) (French)	7F	7F	Identical
Device Length	30 cm	30 cm	Identical
Shaft Material	Pebax 72D SA01, BaSO4 Loaded	Pebax 72D SA01, BaSO4 Loaded	Identical
Deflection (Y/N)	No	No	Identical
Side Port for Flush	Yes	Yes	Identical
Guide wire Compatibility	0.038 in.	0.038 in.	Identical

510(K) SUMMARY

Substantial Equivalence Table (continued)			
Feature	**Subject Device** **AcQRef Introducer Sheath** **TBD**	**Predicate Device** **AcQRef Introducer Sheath** **(K171557)**	**Analysis of Differences**
Dilator, Locking Feature	Yes Locking feature	No Locking feature	The subject device has a lock-in feature. This change does not raise new questions of safety and efficacy. The Dilator functions the same and has the same purpose as the cleared dilator.
Dilator Material	HDPE	Polypropylene	All devices use biocompatible polymer material.
Electrodes	Yes (1x 90/10 Pt-Ir) Sensing Only	Yes (4x 90/10 Pt-Ir) Sensing Only	The subject device is simplified It has only 1 of the original 4 electrodes. This change does not raise any new questions of safety or efficacy.
Electrode Material	Platinum / iridium	Platinum / iridium	Identical
Connection to Recording System or Mapping System	Yes	Yes	Identical
Radiopaque Elements	Yes	Yes	Identical
Anatomical location	Peripheral (Venous)	Peripheral (Vascular)	Identical
Package Contents	Introducer sheath, Guidewire, Dilator	Introducer sheath, Guidewire, Dilator	Identical
Sterilization Method	EtO	EtO	Identical
Sheath Hemostasis Control	Yes	Yes	Identical
Biocompatible Blood, Body and Fluid Contacting Materials	Yes	Yes	Identical
Shelf Life	24 months	24 months	Identical

510(K) SUMMARY

Substantial Equivalence Table (continued)			
Feature	**Subject Device** **AcQRef Introducer Sheath** **TBD**	**Predicate Device** **AcQRef Introducer Sheath** **(K171557)**	**Analysis of Differences**
Connector Cable	1 (yellow)	2 (1 yellow and 1 blue)	The subject device has been simplified. This change does not raise new questions of safety and efficacy.

SUBSTANTIAL EQUIVALENCE

The indication for use of the subject device 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. The assessment of non-clinical performance data demonstrates that the modified AcQRef® Introducer Sheath does not change the fundamental scientific technology of the device.

PERFORMANCE DATA [807.92(B)]

All necessary bench testing was conducted on the modified AcQRef Introducer Sheath to support a determination of substantial equivalence to the predicate device. Verification and validation studies demonstrated that the modified device met the pre-determined acceptance criteria. The results passed to support a determination of substantial equivalence.

CONCLUSION [807.92(B)(3)]

The AcQRef® Introducer Sheath is substantially equivalent in its intended use, technological characteristics and performance to the previously cleared AcQRef® Introducer Sheath (K171557). The subject device has the same fundamental technological characteristics, principles of operation, specifications and is biocompatible to perform per its intended use.