February 6, 2018

Acutus Medical, Inc.
Brenda Clay
Regulatory Affairs Manager
2210 Faraday Ave., Suite 100
Carlsbad, California 92008

Re: K171557
Trade/Device Name: AcQRef Introducer Sheath
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: January 9, 2018
Received: January 10, 2018

Dear Brenda Clay:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

for

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K171557

Device Name
Acutus Medical 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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:

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"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."

510(k) SUMMARY

510(k) Notification K K171557

GENERAL INFORMATION [807.92(a)(1)]

Applicant:

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

Contact Person:

Brenda Clay
Regulatory Affairs Manager
Acutus Medical, Inc.
2210 Faraday Ave., Suite 100
Carlsbad, CA 92008
USA
Phone: 1-442-232-6161
FAX: 1-442-232-6081
Email: Brenda.Clay@acutus.com

Date Prepared: May 26, 2017

DEVICE INFORMATION [807.92(a)(2)]

Trade Name:

AcQRef Introducer Sheath

Generic/Common Name:

Catheter introducer

Classification:

21 CFR 870.1340

Product Code:

DYB

510(k) SUMMARY

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

The predicate device to support substantial equivalence of the AcQRef Introducer Sheath is the Galt Medical Corp. Catheter Introducer, marketed as the Hemostasis Valve Catheter Introducer Set, cleared under K043525. This 510(k) is also citing the St. Jude Agilis ES Steerable Introducer cleared under K103083 as a secondary predicate (reference device).

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, electrodes, and attached extension cable for electrode connectivity. The AcQRef Introducer Sheath consists of the following components:

- One (1) 7Fr Introducer Sheath with electrodes and connection cable
- One (1) 7Fr Vessel Dilator
- One (1) Guide wire - 0.038 in, J-tip

The AcQRef Introducer Sheath is compatible for use with the AcQMap® High Resolution Imaging and Mapping System.

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 – Regulatory Information

Feature	Proposed Device AcQRef Introducer Sheath (K_____)	Predicate Device Galt Medical Corp. Catheter Introducer K043525	Reference Device Agilis™ ES Steerable Introducer K103083	Analysis of Differences
Classification	21 CFR § 870.1340	21 CFR § 870.1340	21 CFR § 870.1340	All devices have the same classification number
Product Code	DYB	DYB	DYB	All devices have the same product code
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 Sheath Introducer System is indicated for use in percutaneous procedures to introduce catheters and other intravascular devices into the vasculature.	The Agilis ES Steerable Introducer is indicated when introducing various cardiovascular catheters into the heart, including the left side of the heart through the interatrial septum. The Introducer may be used for recording intracardiac signals and for cardiac stimulation during electrophysiology studies.	Similar indication for use language compared to the predicate. Proposed indications for use fall within the intended use for the predicate device and also includes language similar to the reference device related to sensing electrical signals. The differences in Indications for Use do not raise different questions of safety or effectiveness.
Intended Use	Catheter delivery system including electrodes for intravenous signal sensing when used with compatible mapping system.	Catheter Delivery System	Mapping/Pacing/ Catheter Delivery System (The steerable introducer, constructed of a polymer shaft that incorporates three platinum-iridium electrodes, the primary use of which is visualization on the EnSite™ System)	Same intended use as the predicate device with regard to catheter delivery. Same intended use as the reference device with respect sensing electrical signals for use with an electrophysiology system.
Device Inner Diameter (ID) (French)	7F	4F to 9F	8.5F	Proposed device French size is within the range of the predicate device
Device Length	30 cm	5 cm to 110 cm	71cm	Proposed device length is within the range of the predicate device

510(k) SUMMARY

Feature	Proposed Device AcQRef Introducer Sheath (K_____)	Predicate Device Galt Medical Corp. Catheter Introducer K043525	Reference Device Agilis™ ES Steerable Introducer K103083	Analysis of Differences
Shaft Material	Pebax 72D SA01, BaSO4 Loaded	unknown polymer	unknown polymer	All devices use biocompatible polymer material.
Deflection (Y/N)	No	No	Yes – Bidirectional (180/90)	Same as the predicate device
Side Port for Flush	Yes	Yes	Yes	All devices have a side port
Guide wire Compatibility	0.038 in.	0.018, 0.021, 0.035, and 0.038 in. per Dilator ID	0.032 in.	Comparable to guidewire compatibility for the predicate
Dilator	Yes	Yes	Yes	All devices have a dilator
Electrodes	Yes (4x 90/10 Pt-Ir) Sensing Only	No	Yes (3)	Proposed device includes electrodes similar to the reference device
Electrode Material	Platinum / iridium	N/A	Platinum / iridium	Same as reference device
Connection to Recording System or Mapping System	Yes	No	Yes	Same as reference device
Radiopaque Elements	Yes	Yes	Yes	All devices have radiopaque elements
Anatomical location	Peripheral (Venous)	Peripheral (Vascular)	Peripheral (Vascular)	All devices have the same anatomical use location
Package Contents	Introducer sheath, Guidewire, Dilator	Introducer sheath, Guidewire, Dilator	Introducer sheath, Guidewire, Dilator	All devices have same main components
Sterilization Method	EtO	EtO	EtO	All devices have same sterilization method
Sheath Hemostasis Control	Yes	Yes	Yes	All devices provide for hemostasis control
Biocompatible Blood, Body and Fluid Contacting Materials	Yes	Yes	Yes	All devices employ biocompatible components for patient contacting components.

510(k) SUMMARY

SUBSTANTIAL EQUIVALENCE

The proposed AcQRef Introducer Sheath was compared to the predicate device with respect to product labeling, intended use, anatomical sites, patient population, performance testing, technological characteristics and safety characteristics. Based on this comparison, there were only minor differences in the technological characteristics between the devices which do not raise any different questions of safety or effectiveness. In addition, AcQRef was compared to a reference device as both devices provide a venous conduit and electrical reference within one product. Thus, AcQRef is substantially equivalent to the predicate device with regard to vascular access and is comparable to the reference device with respect to the sensing of electrical signals.

PERFORMANCE DATA [807.92(B)]

All necessary testing was conducted on the AcQRef Introducer Sheath to support a determination of substantial equivalence to the predicate device.

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

Extensive performance bench testing was conducted on the AcQRef Introducer Sheath. This testing was performed to ensure that the AcQRef Introducer Sheath performs as intended. The nonclinical testing included:

- Packaging and Shelf-Life
- Sterilization
- Biocompatibility
- Surface, Dimensional, and Electrical Integrity
- Valve Air Leak Test
- Simulated Use Test
- Pressure Leak Test
- Flexion and Fatigue
- Electrical Safety
- Corrosion Resistance
- Pull Strength
- Design validation testing in an animal model

The collective results of the nonclinical testing demonstrate that the materials chosen, the manufacturing processes, and design of the AcQRef Introducer Sheath meet the established specifications necessary for consistent performance during its intended use. In addition, the collective bench testing demonstrates that the AcQRef device does not raise different questions of safety or effectiveness for percutaneous catheter introduction into the vasculature.

510(k) SUMMARY

[807.92(b)(2)] Clinical Testing Summary:

No clinical testing is being submitted to support review of this 510(k) premarket notification.

CONCLUSIONS [807.92(b)(3)]

Extensive nonclinical testing has been performed on the AcQRef Introducer Sheath to evaluate the overall performance of the device. The collective results confirm that the AcQRef Introducer Sheath is safe meets its specifications, is biocompatible, and exhibits the required mechanical and functional characteristics to perform per its intended use.

SUMMARY

The AcQRef Introducer Sheath is substantially equivalent to the predicate device.