Rivanna Medical, LLC
% William Mauldin, Ph.D.
Chairman, CEO, and Co-founder
107 East Water Street
CHARLOTTESVILLE VA 22902

October 20, 2017

Re: K171594
Trade/Device Name: Accuro
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: IYO, ITX
Dated: September 15, 2017
Received: September 21, 2017

Dear Dr. Mauldin:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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)*
K171594

Device Name
Accuro

Indications for Use *(Describe)*
The Accuro is intended for diagnostic ultrasound imaging of the human body in the following clinical applications: Abdominal, Musculoskeletal (conventional and superficial), Cardiac, Peripheral Vascular, Small Organs (e.g. thyroid, breast), and Pediatrics. A typical examination using the Accuro is guidance of neuraxial anesthesia.

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.

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:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
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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."

1.3. Indications for Use

1.3.1. 510(k) Indications for Use Form

Diagnostic Ultrasound Indications for Use Form

Accuro

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	P						2,3
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	N						2,3,4
	Small Organ[1] (Specify)	N						2,3
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card)							
	Musculo-skeletal (**Conventiona**l)	P						2,3,4
	Musculo-skeletal (**Superficial**)	P						2.3,4
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult	P						
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel	P						2,3
	Other (Specify)							

N = new indication; P = previously cleared by FDA in K132736

*Examples of other modes of operation may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and Color Velocity Imaging

Notes:

[1] Small Organ includes thyroid and breast

[2] Image guidance for freehand needle/catheter placement

[3] BoneEnhance® (image post-processing)

[4] SpineNav3D™ (image post-processing)

RIVANNA®

510 (k) Summary
21 CFR 807.92

Accuro

General Provisions	Submitter Name: Submitter Address:	Rivanna Medical, LLC 107 E Water St Charlottesville, VA 22932
	Contact Person:	Will Mauldin, PhD Chairman, CEO, and Co-founder (t) 800-645-7508 x701 (e) wmauldin@rivannamedical.com
	Date of Preparation:	09 May 2017
Subject Device	Trade Name:	Accuro
	Classification Name:	IYO21 CFR892.1560 Ultrasonic Pulsed Echo Imaging System ITX21 CFR892.1570 Diagnostic Ultrasonic Transducers
Predicate Device	Trade Name:	Accuro 3000 Ultrasound Scanner
	Classification Name:	IYO21 CFR892.1560 Ultrasonic Pulsed Echo Imaging System ITX21 CFR892.1570 Diagnostic Ultrasonic Transducer
	Premarket Notification:	K132736, March 11th 2014
	Manufacturer:	Rivanna Medical, LLC

Predicate Device	Trade Name:	Vscan Extend
	Classification Name:	IYO21 CFR892.1560 Ultrasonic Pulsed Echo Imaging System ITX21 CFR892.1570 Diagnostic Ultrasonic Transducer
	Premarket Notification:	K161588, August 31nd 2016
	Manufacturer:	GE Medical Systems Ultrasound & Primary Care Diagnostics, LLC

RIVANNA®

Device Description	The Accuro is a hand-held device that features real-time B-mode ultrasound imaging only. Additional features include a compact size and a simple user interface.
Indications for Use	The Accuro is intended for diagnostic ultrasound imaging of the human body in the following clinical applications: Abdominal, Musculoskeletal (conventional and superficial), Cardiac, Peripheral Vascular, Small Organs (e.g. thyroid, breast), and Pediatrics. A typical examination using the Accuro is guidance of neuraxial anesthesia.
Technological Characteristics	Technological characteristics of the Accuro are equivalent with respect to the basic design and function of the predicate devices. This 510(K) submission expands the Indications for Use of the Accuro 3000 Ultrasound Scanner (K132736). The Accuro has no technologies, features, or indications for use not commonly used in the practice of diagnostic ultrasound.
Safety & Performance Tests	Verification and Validation activities were designed and performed to demonstrate that the Accuro met pre-determined performance specifications. The following standards in conjunction with in-house protocols were used to determine appropriate methods for evaluating the performance of the device:

IEC60601-1:2005, Medical Electrical Equipment – Part 1: General Requirements for Safety and Essential Performance
IEC60601-1-2:2007, Medical Electrical Equipment – Part 1-2: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility Requirements and Tests
IEC60601-2-37:2007, Medical Electrical Equipment – Part 2-37: Particular Requirements for the Safety of Ultrasonic Medical Diagnostic and Monitoring Equipment
ISO14971:2007, Application of risk management to medical devices, Second edition
NEMA UD-2:2004: Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment
NEMA UD-3:2004: Standard for Real-Time Display of Thermal and Mechanical Acoustic Output indices on Diagnostic Ultrasound Equipment
ISO 10993-1: Biological Evlauation of Medical Devices- Part 1: Evaluation and Testing Within a Risk Management Process

Summary of Substantial Equivalence	Based on the indications for use, technological characteristics, and safety and performance testing, the subject Accuro, met the minimum requirements that are considered adequate for its intended use and is substantially equivalent in design, principles of operation and indications for use to the predicate devices.