April 09, 2026

Rivanna Medical, Inc.
F. William Mauldin
Chairman, Co-founder, and CEO
2400 Hunters Way
Charlottesville, Virginia 22911

Re: K254021
Trade/Device Name: Accuro XV
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic Pulsed Echo Imaging System
Regulatory Class: Class II
Product Code: IYO, ITX
Dated: December 16, 2025
Received: December 16, 2025

Dear F. William 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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

MARJAN NABILI -S for

Yanna Kang, Ph.D.
Assistant Director
Mammography and Ultrasound Team
DHT8C: Division of Radiological
Imaging and Radiation Therapy Devices
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K254021

Please provide the device trade name(s).

Accuro XV

Please provide your Indications for Use below.

The Accuro XV is an ultrasound imaging system for use by qualified and trained healthcare professionals. Accuro XV features a conformable three-dimensional medical ultrasound probe that automates large field-of-view image acquisitions after initial patient positioning. Accuro XV supports B-mode imaging for clinical applications that include: musculoskeletal conventional and superficial.

Please select the types of uses (select one or both, as applicable).

- [x] Prescription Use (21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

This summary of safety and effectiveness is provided as part of this Premarket Notification in compliance with 21 CFR, Part 807, Subpart E, Section 807.92.

Date:	December 19, 2025
Submitter:	Rivanna Medical, Inc. 2400 Hunters Way Charlottesville, VA 22911
Primary Contact Person:	F. William Mauldin, Jr. CEO Rivanna Medical, Inc. T: 800-645-7508

Subject Device Trade Name: Accuro XV

Common Name: Diagnostic Ultrasound System
Device Class: Class II
Regulation: 21CFR 892.1560, Ultrasonic Pulsed Echo Imaging System;
21 CFR 892.1570, Diagnostic Ultrasound Transducer
Product Code: IYO; ITX

Legally Marketed Predicate Device(s):

Primary Predicate Device: K243937 Accuro 3S
Common Name: Diagnostic Ultrasound System
Device Class: Class II
Regulation: 21CFR 892.1560, Ultrasonic Pulsed Echo Imaging System;
21 CFR 892.1570, Diagnostic Ultrasound Transducer
Product Code: IYO; ITX

Reference Device: K092271 GE LOGIQ E9 BT2010 Diagnostic Ultrasound System
Common Name: Diagnostic Ultrasound System
Device Class: Class II
Regulation: 21 CFR 892.1550, Ultrasound Pulsed Doppler Imaging System;
21CFR 892.1560, Ultrasonic Pulsed Echo Imaging System;
21 CFR 892.1570, Diagnostic Ultrasound Transducer
Product Code: IYN; IYO; ITX

Device Description:

The Accuro XV is an ultrasound imaging device intended for use by qualified and trained healthcare professionals in hospital or medical clinic environments. The device offers B-mode imaging.

The Accuro XV is a portable system with a small footprint that can be easily maneuvered within the intended use environment and at the point of care. Accuro XV supports image acquisition in two different configurations: (1) patient gantry assembly configuration and (2) detachable free-hand configuration. The device features a touchscreen interface and an integrated battery pack that allows the system to operate without wall power. Accuro XV interfaces with healthcare IT networks to implement DICOM-based patient and image archival workflows, with image storage in an external PACS. The device utilizes two identical volumetric imaging probes.

The Accuro XV volumetric imaging probes contain linear arrays with the following specifications: 384 elements, 6.5 MHz nominal center frequency, and 360-micron pitch. Volumetric scans are automatically acquired by motorized linear translation of the array over an extent of 10 cm. A compliant polyurethane stand-off medium creates a conformable patient contact surface to improve acoustic coupling with irregular patient contact anatomies.

User documentation is available electronically.

Intended Use/Indications for Use:

The Accuro XV is an ultrasound imaging system for use by qualified and trained healthcare professionals. Accuro XV features a conformable three-dimensional medical ultrasound probe that automates large field-of-view image acquisitions after initial patient positioning. Accuro XV supports B-mode imaging for clinical applications that include: musculoskeletal conventional and superficial.

Comparison to Predicate Device(s):

Accuro XV is substantially equivalent to the predicate device in terms of technological characteristics and safety and effectiveness.

The Accuro XV system intended use, intended user, patient population, and use environment are shared with the predicate device, Accuro 3S (K243937), and reference device, Logiq E9 (K092271). Differences include mechanical form factor of the Accuro XV cart design, computer hardware, and user interface design.

The key difference between the subject device and predicate(s) is the Accuro XV volumetric imaging probe.

The two identical Accuro XV volumetric imaging probes contain linear arrays with the following specifications: 384 elements, 6.5 MHz nominal center frequency, and 360-micron pitch. Volumetric scans are automatically acquired by motorized linear translation of the array over an extent of 10 cm. A compliant polyurethane stand-off medium creates a conformable patient contact surface to improve acoustic coupling with irregular patient contact anatomies. User activated buttons are located on the probes for convenient initiation of imaging acquisition. The probes are intended to acquire images either in a detachable free-hand configuration or when docked on the patient

gantry assembly of the system cart. The patient gantry can be raised or lowered to conveniently access patient anatomy. Accuro 3S (K243937) uses similar hardware and software to perform musculoskeletal imaging using a Dual-Array convex probe. Reference device, Logiq E9 (K092271), is cleared with similar three-dimensional scanning probes, including RSP6-16-D and RAB2-5-D, which are operated by motorized mechanical means. The differences between the Accuro XV volumetric imaging probes and the Logiq E9 reference device probes include differences in geometry, patient contact material, and conformability. Non-clinical testing for performance and safety has been conducted to ensure that no new risks are introduced due to these geometrical and material differences. This includes performance testing and testing to IEC 60601-2-37 and application of ISO 14971 for risk management.

Differences in design between the Accuro XV and predicate device do not raise any new issues related to safety or effectiveness.

Summary of Non-Clinical Tests:

The Accuro XV has been evaluated for acoustic output, cleaning/disinfection and electrical, thermal, mechanical, and EMC safety. The device has been found to conform to applicable medical device safety standards. Patient contact materials are biocompatible.

Validation testing was performed to ensure that Accuro XV meets the requirements of the intended end users for specified clinical applications.

Usability testing was conducted in accordance with the FDA recognized standard, IEC 60601-1-6, to evaluate the usability of the Accuro XV under realistic conditions and to validate that the intended users can use the Accuro XV safely.

Assurances of quality were further established by employing the following elements of product design and development in accordance with 21 CFR 820 and ISO 14971:2019:

- Risk analysis
- Requirements development
- Design reviews
- System validation including accuracy and performance validation
- Software verification
- Hardware verification
- Safety compliance verification

Accuro XV complies with the following FDA guidance and recognized standards:

- Marketing Clearance of Diagnostic Ultrasound Systems and Transducers- Guidance for Industry and Food and Drug Administration Staff, issued on February 21, 2023

- IEC 60601-1 Edition 3.2 2020-08, Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance. [19-49]
- IEC 60601-1-2 Edition 4.1 2020-09, Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements and Tests. [19-36]
- IEC 60601-1-6 Edition 3.2 2020-07, Medical Electrical Equipment – Part 1-6: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Useability. [5-132]
- IEC 60601-2-37 Edition 2.1 2015, Medical Electrical Equipment – Part 2-37: Particular Requirements for the Safety of Ultrasonic Medical Diagnostic and Monitoring Equipment. [12-293]
- IEC 62304, Edition 1.1 2015-06, Medical Device Software – Software Life Cycle Processes. [13-79]
- IEC 62366-1 Edition 1.1 2020-06, Medical devices - Part 1: Application of Usability Engineering to Medical Devices. [5-129]
- IEC 62359 Edition 2.1 2017-09, Ultrasonics - Field Characterization – Test Methods for the Determination of Thermal and Mechanical Indices Related to Medical Diagnostic Ultrasonic Fields. [12-316]
- ISO 10993-1 Fifth edition 2018, Biological Evaluation of Medical Devices-Part 1: Evaluation and Testing Within a Risk Management Process. [2-258]
- ISO 14971 Third edition 2019-12, Application of Risk Management to Medical Devices. [5-125]
- NEMA UD 2-2004 (R2009), Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment Revision 3. [12-105]
- NEMA PS 3.1 - 3.20e, Digital Imaging and Communications in Medicine (DICOM) Set. [12-352]
- AAMI TIR69:2017(R2020), Technical Information Report Risk management of radio-frequency wireless coexistence for medical devices and systems. [19-22]

Summary of Clinical Tests:

The subject of this pre-market submission did not require clinical studies to support the determination of substantial equivalence.

Conclusion:

Accuro XV exhibits the same technology characteristics and indications for use as legally marketed predicate devices and testing demonstrates substantially equivalent performance. Therefore, Rivanna Medical, Inc. considers Accuro XV as substantially equivalent.