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

October 20, 2026

Re: K262093
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, QIH
Dated: September 25, 2026
Received: September 28, 2026

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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. 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 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (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 ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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,

Digitally signed by Michael D. O'hara -S
Date: 2026.10.20 12:32:15 -04'00'

For

Yanna Kang
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.	K262093

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.

BoneEnhance® is a software module available during review of Accuro XV volumetric image acquisitions. The software uses a machine learning algorithm to segment musculoskeletal anatomy and to support visualization of skeletal anatomy in three dimensions. BoneEnhance® is indicated for adults only and for the following anatomic areas of interest: wrist/forearm and ankle/lower leg.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☒ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

K262093

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: June 22, 2026

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;
21 CFR 892.2050, Medical Image Management and Processing System
Product Code: IYO; ITX; QIH

Legally Marketed Predicate Device(s):

Primary Predicate Device: K254021 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

Reference Device: K243937 Accuro 3S
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: 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 with anatomical segmentation and 3D indicator software to facilitate image review.

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 acoustic stand-off medium creates a conformable patient contact surface to improve acoustic coupling with irregular patient contact anatomies.

BoneEnhance® technology applies machine learning segmentation to identify bone and surrounding tissues within volumetric ultrasound datasets. The system uses image processing to apply enhancement techniques to highlight bone structures, while preserving underlying image formation and without altering original anatomical data.

The Accuro XV processes volumetric ultrasound data to produce 3D image indicators of bone and soft tissue captured within the ultrasound data, supporting side-by-side qualitative assessment of anatomy contained within the 2D imaging planes.

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.

BoneEnhance® is a software module available during review of Accuro XV volumetric image acquisitions. The software uses a machine learning algorithm to segment musculoskeletal anatomy and to support visualization of skeletal anatomy in three dimensions. BoneEnhance® is indicated for adults only and for the following anatomic areas of interest: wrist/forearm and ankle/lower leg.

Comparison to Predicate Device(s):

The Accuro XV system intended use, intended user, patient population, and use environment are shared with the predicate device, Accuro XV (K254021), and reference devices, Accuro 3S (K243937) and LOGIQ E9 (K092271).

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

The Accuro XV system is identical to the predicate device Accuro XV (K254021) but with key differences including the addition of the BoneEnhance® segmentation software and 3D indicator feature. The BoneEnhance® technology is similar to the AnatomyView technology on the reference device Accuro 3S (K243937). Both technologies are machine learning segmentation algorithms applied to ultrasound images. In both technologies, the algorithms are designed for segmenting and placing graphical overlays on bone and soft tissue structures while not obscuring the underlying anatomy. Both technologies are used to assist workflow by highlighting musculoskeletal anatomy to support localization in ultrasound imaging during clinical evaluation of musculoskeletal conventional and superficial anatomy. Neither is technology intended for diagnostic purposes. The differences between BoneEnhance® and AnatomyView include implementation during different clinical workflows and on different anatomies, with AnatomyView segmenting spinal structures to support ultrasound-guided procedures, and BoneEnhance® segmenting extremity musculoskeletal structures to support ultrasound image review.

The volumetric rendering software on the Accuro XV subject device is substantially equivalent to the Easy 3D software on the LOGIQ E9 reference device (K092271). Both technologies provide 3D visualization of anatomical structures within volumetric ultrasound datasets to support localization and assessment of the corresponding 2D ultrasound image. Both technologies also allow side-by-side display of the 2D ultrasound image and the associated 3D rendering.

Non-clinical testing for performance and safety has been conducted to ensure that no new risks are introduced due to these technological differences. This includes performance testing and testing to IEC 60601-2-37 and application of ISO 14971 for risk management.

Differences in technologies between the Accuro XV and predicate devices 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.

Volumetric rendering was evaluated through software and system tests of anatomical orientation and display synchronization, together with a separate image-review assessment involving clinical end users. The orientation and synchronization tests met their acceptance criteria. In the image-review assessment, rendering quality was rated Acceptable or better in > 80% of ratings. Participants agreed or strongly agreed that the rendering aided image interpretation in > 80% of ratings and provided insight into adjacent frames in > 80% of ratings. These findings support the rendering's intended role as a qualitative aid to high-level anatomical orientation and navigation.

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. [12-363]
- AAMI TIR69:2017(R2020), Technical Information Report Risk management of radio-frequency wireless coexistence for medical devices and systems. [19-22]

Summary of AI Tests:

Standalone Performance Validation

BoneEnhance is an AI/ML-based image segmentation function that processes volumetric B-mode ultrasound data to identify and segment specified musculoskeletal anatomical structures of the wrist/forearm and ankle/lower leg. Standalone performance was evaluated using a test dataset that was independent of the data used for model training and tuning.

The validation Test Dataset included 233 volumetric ultrasound datasets comprising approximately 69,900 images from 173 adult subjects, including 111 wrist/forearm datasets and 122 ankle/lower leg datasets. Test data were collected at five geographically diverse U.S. sites. The data used for model training and tuning were separate from the validation Test Dataset.

Data were acquired using Accuro XV systems by trained operators following a standardized acquisition protocol. Data collection included multiple Accuro XV devices and the anterior, posterior, lateral, and medial acquisition views applicable to the intended use. The validation data provided representation across all four acquisition views for both wrist/forearm and ankle/lower leg testing.

The Validation Test Report confirms that the clinical protocol requirements for operator training, multisite data collection, use of multiple devices, and standardized acquisition were met.

Reference-standard anatomical segmentations were established through a multi-stage expert annotation and review process involving qualified radiologists and ultrasound reviewers. Test annotations underwent expert review before being accepted for use in the standalone performance evaluation.

Validation Population

The validation population included 173 adult subjects, including 85 male subjects (49.1%) and 88 female subjects (50.9%). There were 81 subjects (46.8%) younger than 40 years, nine subjects (5.2%) ranged from 40 to 49 years, 52 subjects (30.1%) ranged from 50 to 64 years, and 31 subjects (17.9%) were 65 years of age or older. BMI was <18.5 kg/m² for two subjects (1.2%), 18.5 to 24.9 kg/m² for 52 subjects (30.1%), 25-29.9 kg/m^2 for 56 subjects (32.4%), and ≥30 kg/m² for 63 subjects (36.4%). The racial distribution included 90 White subjects (52.0%), 32 Black subjects (18.5%), 37 subjects categorized as Other (21.4%), 8 Asian subjects (4.6%), and 6 subjects categorized as American Indian (3.5%). Eighty subjects (46.2%) were Hispanic and 93 subjects (53.8%) were non-Hispanic.

Characteristic	Validation Population
Subjects	173
Male	85 (49.1%)
Female	88 (50.9%)
Age < 40 years	81 (46.8%)
Age 40-49 years	9 (5.2%)
Age 50-64 years	52 (30.1%)
Age ≥ 65 years	31 (17.9%)
BMI < 18.5 kg/m^2	2 (1.2%)
BMI 18.5-24.9 kg/m^2	52 (30.1%)
BMI 25-29.9 kg/m^2	56 (32.4%)
BMI ≥ 30 kg/m^2	63 (36.4%)
White	90 (52.0%)
Black	32 (18.5%)
Asian	8 (4.6%)
American Indian	6 (3.5%)
Other Race/Ethnicity	37 (21.4%)
Hispanic	80 (46.2%)
Non-Hispanic	93 (53.8%)

Performance Metrics and Acceptance Criteria

BoneEnhance standalone performance was evaluated for each anatomical segmentation output using Per-Volume Label Prediction Accuracy, DICE Coefficient, and Hausdorff 95th percentile distance (HD95). Label-specific DICE and HD95 acceptance criteria were prospectively established through intended-user evaluation of segmentation outputs representative of the intended qualitative visualization function. Because the clinical and geometric characteristics of the segmented structures differ, DICE and HD95 acceptance criteria were label-specific. A minimum Per-Volume Label Prediction Accuracy of 70% was prespecified for each anatomical label. The range of observed performance across wrist/forearm and ankle/lower leg anatomical labels are summarized below.

Performance Metric	**Observed Performance Across Anatomical Labels Mean [Range]**
Per-Volume Label Prediction Accuracy	99.0% [95.1%-100%]
DICE Coefficient	0.75 [0.64-0.86]
HD95	4.58 mm [2.26-7.03 mm]

Performance for every anatomical label met its applicable prespecified acceptance criteria.

Subgroup and Confounder Analyses

BoneEnhance performance was evaluated across demographic and acquisition-related subgroups relevant to the intended-use population. The validation population included representation by sex, age, BMI, race/ethnicity, clinical presentation, and acquisition view. Age and biological sex were prospectively identified as primary subgroup variables because of their potential association with clinically relevant differences in bone density and morphology that could affect algorithm performance. Specifically, subjects ≥50 years of age were evaluated as a primary subgroup due to the increased prevalence of age-related osteopenic and osteoporotic changes, and female subjects were evaluated as a primary subgroup due to the higher prevalence of osteopenic, osteoporotic, and degenerative skeletal changes.

Across the validation dataset, no consistent trend toward reduced BoneEnhance performance was observed with increasing age or by biological sex. Post hoc analyses by BMI category (<18.5, 18.5–24.9, 25–29.9, and ≥30 kg/m²) likewise identified no significant differences in BoneEnhance performance. In addition, all evaluable acquisition-view subgroup performance tests met the applicable prespecified acceptance criteria. The Achilles tendon label is available and has been validated only for the posterior ankle acquisition view. As a result, this anatomy in the Posterior Ankle acquisition-view subgroup has only been validation in the Posterior view.

The validation database also included a broad range of clinical findings and anatomical confounders. Of the validation cases, 71.7% had at least one abnormal finding and 28.3% had no identified abnormal finding. Findings represented in the validation population included soft-tissue abnormalities in 43.9% of cases, fracture in 33.5%, degenerative change in 24.9%,

osteoporosis/osteopenia in 13.9%, remote or chronic ossific fragments in 10.4%, ligamentous injury in 4.6%, surgical implant in 3.5%, and other less-frequent abnormalities.

The validation population therefore included both normal and abnormal examinations and represented clinical conditions that can alter anatomical appearance or ultrasound image interpretation, including fracture, degenerative change, reduced bone density, soft-tissue pathology, postoperative hardware, and altered joint alignment. BoneEnhance performance was characterized across the demographic, acquisition, and clinical variability represented in this validation population.

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.