



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

July 24, 2026

Re: K253452
Trade/Device Name: Accuro 3S
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic Pulsed Echo Imaging System
Regulatory Class: Class II
Product Code: IYO, ITX
Dated: June 30, 2026
Received: June 30, 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.

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: 2026.07.24 12:51:36 -04'00' 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.

K253452

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Please provide the device trade name(s).

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Accuro 3S

Please provide your Indications for Use below.

?

The Accuro 3S is a diagnostic ultrasound imaging system for use by qualified and trained healthcare professionals. Accuro 3S is intended to be used in a hospital or medical clinic environment at the point of care.

Accuro 3S supports B-mode imaging and a SpineNav-AI™ image processing software. Accuro 3S clinical applications include: musculoskeletal conventional and superficial, and guidance for needle placement. A typical examination using Accuro 3S is guidance of neuraxial anesthesia.

SafeTrack™ is intended to provide healthcare professionals with visual tools for magnetic tracking of a needle with respect to ultrasound image data in musculoskeletal conventional and superficial applications.

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

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
☐ Over-The-Counter Use (21 CFR 801 Subpart C)

?



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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: September 30, 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 3S

Common/Usual Name: Diagnostic Ultrasound System and Transducer
Classification Name: Ultrasound Pulsed Echo Imaging System
Device Class: Class II
Product Codes: Ultrasound Pulsed Echo Imaging System, 21CFR 892.1560, 90-IYO;
Diagnostic Ultrasound Transducer, 21 CFR 892.1570, 90-ITX

Legally Marketed Predicate Device(s):

Primary Predicate Device: K243937 Accuro 3S
Common/Usual Name: Diagnostic Ultrasound System and Transducer
Classification Name: Ultrasound Pulsed Echo Imaging System
Device Class: Class II
Product Code: Ultrasound Pulsed Echo Imaging System, 21CFR 892.1560, 90-IYO;
Diagnostic Ultrasound Transducer, 21 CFR 892.1570, 90-ITX

Reference Device: K142443 Site~Rite® 6 Ultrasound System with Pinpoint™ GT Technology
Common/Usual Name: Diagnostic Ultrasound System
Classification Name: Ultrasound Pulsed Echo Imaging System
Device Class: Class II
Product Code: Ultrasound Pulsed Echo Imaging System, 21 CFR 892.1560, 90-IYO;
Diagnostic Ultrasound Transducer, 21 CFR 892.1570, 90-ITX

Device Description:

The Accuro 3S 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, a SpineNav-AI™ image guidance software tool, and SafeTrack™ needle tracking technology.



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The Accuro 3S is a portable system with a small footprint that can be easily maneuvered within the intended use environment and at the point of care. The device features a touchscreen interface and articulated monitor arm to optimize viewing angle. An integrated battery pack allows the system to operate without wall power. Accuro 3S interfaces with healthcare IT networks to implement DICOM-based patient and image archival workflows, with image storage in an external PACS. The device utilizes a Dual-Array™ convex probe.

The Accuro 3S Dual-Array™ probe comprises a side-by-side convex transducer array design. Each convex array has identical specifications: 64 elements, 3.5 – 4.0 MHz nominal center frequency, 480 micron pitch, and 50 mm radius of curvature.

SpineNav-AI is an automated software tool that utilizes machine learning technologies to facilitate workflows associated with musculoskeletal imaging assessments of the lumbar spine.

SafeTrack is a needle tracking technology that consists of software integrated into the ultrasound unit and sensors embedded into the Dual-Array ultrasound probe. The sensors detect a magnetic field emitted by the needle, and the software processes this data to display the needle tip location and trajectory on the ultrasound image in real time. SafeTrack is intended to only be used with the SafeTrack-compatible needles included in the Accuro 3S Needle Guide Kit. Compatibility and performance have not been established with any other needles.

Intended Use/Indications for Use:

The Accuro 3S is a diagnostic ultrasound imaging system for use by qualified and trained healthcare professionals. Accuro 3S is intended to be used in a hospital or medical clinic environment at the point of care.

Accuro 3S supports B-mode imaging and a SpineNav-AI™ image processing software. Accuro 3S clinical applications include: musculoskeletal conventional and superficial, and guidance for needle placement. A typical examination using Accuro 3S is guidance of neuraxial anesthesia.

SafeTrack™ is intended to provide healthcare professionals with visual tools for magnetic tracking of a needle with respect to ultrasound image data in musculoskeletal conventional and superficial applications.

Comparison to Predicate Device(s):

Accuro 3S is substantially equivalent to the predicate device in terms of technological characteristics and safety and effectiveness.

The Accuro 3S system is identical to the predicate device Accuro 3S (K243937) but with the addition of the SafeTrack needle guidance technology. The SafeTrack technology is similar to the Pinpoint GT technology on the reference device Site-Rite 6 (K142443). Both technologies possess a probe with embedded magnetic sensors. In both technologies, the magnetic sensors detect a



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magnetic signal emitted by the needle and use software to overlay a representation of the needle tip and trajectory on the ultrasound display screen. Both technologies are intended to provide healthcare professionals with visual tools for magnetic tracking of a needle with respect to ultrasound image data. The differences between SafeTrack and Pinpoint GT technology include implementations on different probe geometries.

Differences in design between the Accuro 3S and predicate device do not raise any new issues related to safety or effectiveness.

Summary of Non-Clinical Tests:

The Accuro 3S 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 3S meets the requirements of the intended end users for specified clinical applications.

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 3S 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]



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- 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 premarket submission, Accuro 3S, did not require clinical studies to support the determination of substantial equivalence.

Conclusion:

Accuro 3S exhibits the same technology characteristics and indications for use as legally marketed predicate and reference devices and testing demonstrates substantially equivalent performance. Therefore, Rivanna Medical considers Accuro 3S as substantially equivalent.