May 23, 2025

Rivanna Medical, Inc.
F. William Mauldin
Chairman, Co-Founder, and CEO
2400 Hunters Way
CHARLOTTESVILLE, VA 22911

Re: K243937
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: April 24, 2025
Received: April 24, 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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 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 systems (QS) regulation (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,

JULIE SULLIVAN -S

Julie Sullivan, Ph.D.
Director
DHT8C: Division of Radiological
Imaging and Radiation Therapy Devices
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243937

Device Name

Accuro 3S

Indications for Use *(Describe)*

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 or catheter placement. A typical examination using Accuro 3S 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.

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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: December 18, 2024

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 Name: Diagnostic Ultrasound System and Transducer
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: K171594 Accuro
Common/Usual Name: Diagnostic Ultrasound System
Classification Name: 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: K220851 Venue
Classification Name: Diagnostic Ultrasound System
Classification Name: Class II
Product Code: Ultrasound Pulsed Doppler Imaging System, 21 CFR 892.1550, 90-IYN;
Ultrasound Pulsed Echo Imaging System, 21CFR 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 and a SpineNav-AI™ image processing software.

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.

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

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.

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 or catheter placement. A typical examination using Accuro 3S is guidance of neuraxial anesthesia.

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 intended use, intended user, patient population, and use environment are shared with the predicate device, Accuro (K171594), and reference device, Venue (K220851). Differences include the mechanical form factor of the Accuro 3S cart-based device, electronic beamformer and computer hardware, and user interface design.

Key differences include the transducer type and SpineNav-AI software navigation tool.

The Dual-Array probe featured on Accuro 3S includes two standard PZT-based transducer arrays with a convex geometry. The two arrays are aligned at the patient contact surface and physically separated with a void, or ‘gap’, between the two convex arrays. Images from both convex arrays are combined, or ‘compounded’, to create a single image in sector-scan format. Accuro (171594) creates similar sector scan images but with a mechanically scanned single-element transducer. Reference device, Venue (K220851) is cleared with a similar convex array transducer (probe name C1-5-RS) with similar nominal center frequency around 3.5MHz, element number, and pitch. Non-clinical testing for performance and safety has been conducted to ensure that no new risks are introduced due to the geometrical differences. This includes performance testing and testing to IEC 60601-2-37 and application of ISO 14971 for risk management.

SpineNav-AI is an improved version of SpineNav3D from predicate device, Accuro (K171594). Whereas SpineNav3D utilizes an analytical algorithm based on template matching routines, SpineNav-AI utilizes machine learning. The navigation tool supports the workflows associated with musculoskeletal imaging assessments of the lumbar spine such as at the scouting stage of a neuraxial anesthesia procedure. The scouting stage of a neuraxial anesthesia procedure is the process of scanning the anatomy to orient the needle approach prior to placement of a catheter in the epidural space or introduction of anesthetic material. The machine learning algorithm at the foundation of SpineNav-AI is a deep convolutional neural network approach to segmenting certain anatomical structures in the lumbar spine and conveying them by way of graphics to the user. A measurement to the epidural space is provided in an identical manner to SpineNav3D on the predicate Accuro (K171594) device. The machine learning algorithm for segmentation of anatomy is similar to the cNerve feature on reference device Venue (K220851) which also segments anatomy related to nerve blocks: popliteal, brachial, and femoral. AI testing was performed with similar methodology to cNerve on the Venue (K220851) to ensure performance meets test criteria and ISO 14971 for risk management was applied to design and labeling ensure that no new risks are introduced.

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]
- 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]

AI Summary of Tests:

SpineNav-AI™ image guidance software tool was validated on a test dataset comprising a diverse range of demographic variables such as gender, age, ethnicity and body mass index (BMI). Test data were collected at seven (7) geographically diverse sites. The test dataset included 120 sequences and 10,080 image frames obtained from a total of 81 individuals.

Ground truth for anatomical labels were established from a panel of three board certified radiologists. Generalizability of the results were assessed among subgroups for gender (M/F), age (< 50 / ≥ 50), and BMI (< 25 / ≥ 25).

Since the intended use is anatomical feature tracking during scouting rather than feature segmentation accuracy for diagnostic purposes, success criteria for each anatomical annotation produced with SpineNav-AI were derived via a preliminary survey with intended users. The preliminary survey established success criteria for per-frame accuracy, per-sequence detection success rate, and DICE. Acceptance criteria for detection of each anatomical feature was 70% per-frame accuracy and 80% per-sequence detection success rate. The range of per-frame accuracy for all anatomical structures was 82.1% - 99.3%; the range of per-sequence detection success rate for all anatomical structures was 91.7% - 100%; and the range of DICE scores for all anatomical structures was 0.64 – 0.87.

The Epidural Region Indicator, derived from SpineNav-AI anatomical segmentations, demonstrated accuracy of 1.61 (± 2.57) mm and 2.42 (± 3.41) mm in the lateral and depth dimensions, respectively, compared to the radiologist panel ground truth. Per-frame detection success rate of the Epidural Region Indicator was 95.5%.

The data used in the training and tuning process comprised 25,536 images from 147 subjects and is completely distinct from the test dataset used for validation.

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, Accuro 3S is substantially equivalent to the predicate device.