June 13, 2025

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

Re: K250469
Trade/Device Name: Accuro® 3S Needle Guide Kit
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: Class II
Product Code: ITX
Dated: May 12, 2025
Received: May 12, 2025

Dear Will 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,

YANNA S. KANG -S

Yanna Kang, Ph.D.
Assistant Director
Mammography and Ultrasound Team
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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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K250469

Device Name
Accuro® 3S Needle Guide Kit

Indications for Use *(Describe)*
The Accuro® 3S Needle Guide Kit is intended to be used with the Accuro® 3S diagnostic ultrasound imaging system.

The Accuro® 3S Needle Guide Kit supports alignment of a needle with the ultrasound imaging plane to assist the healthcare professional in placing the tip of a needle relative to a specific anatomical structure. The elastic bands on the Patient Drape are intended to stabilize the positioning of the Accuro® 3S Needle Guide.

The Accuro® 3S Probe Cover sheathes the transducer and isolates a needle insertion site from microbial and other contaminants.

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.

K250469

510(k) Summary

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 12th, 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 Needle Guide Kit

Common Name: Transducer, Ultrasonic, Diagnostic
Device Class: Class II
Regulation: 21 CFR 892.1570, Diagnostic Ultrasonic Transducer
Product Codes: ITX

Legally Marketed Predicate Device:

Primary Predicate Device: K171348 Pinpoint™ GT Needle Guide Kits
Common Name: Transducer, Ultrasonic, Diagnostic
Device Class: Class II
Regulation: 21 CFR 892.1570, Diagnostic Ultrasonic Transducer
Product Codes: ITX

Device Description:

The Accuro® 3S Needle Guide Kit consists of the following single use sterile disposable components: Accuro® 3S Needle Guide with integrated probe cover, conductive ultrasound gel, and a patient drape with two integrated probe elastic bands.

The kit components are assembled into a sterilized CSR Wrap then packaged in a sterile tray.

The final kit is sterilized under ethylene oxide.

Intended Use/Indications for Use:

The Accuro® 3S Needle Guide Kit is intended to be used with the Accuro® 3S diagnostic ultrasound imaging system.

The Accuro® 3S Needle Guide Kit supports alignment of a needle with the ultrasound imaging plane to assist the healthcare professional in placing the tip of a needle relative to a specific anatomical structure. The elastic bands on the Patient Drape are intended to stabilize the positioning of the Accuro® 3S Needle Guide.

The Accuro® 3S Probe Cover sheathes the transducer and isolates a needle insertion site from microbial and other contaminants.

Comparison to Predicate Device(s):

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

The Accuro® 3S Needle Guide Kit indications for use is similar to the predicate device, Pinpoint™ GT Needle Guide Kits (K171348). Both are indicated to cover an ultrasound probe and isolate from microbial and other contaminants, and both have needle guides to assist with placement of a needle to a specific anatomical structure. Both subject and predicate devices are prescription use and intended for the same use environments.

The key difference between the subject and predicate device is the inclusion of a patient drape with bands that support the needle guide positioning. The elastic bands are integrated into the patient drape and do not come in direct contact with the patient. The intended function of the elastic bands is to provide pressure against the back of the transducer probe to stabilize its position, and thus the Needle Guide position, against the skin during ultrasound imaging and needle advancement. Non-clinical testing for performance, including usability, and safety has been conducted to ensure that no new risks are introduced due to the addition of elastic bands on the Patient Drape. This includes verification testing and application of ISO 14971 for risk management.

Summary of Non-Clinical Tests:

Design functionality of the subject device was tested to ensure that it meets the requirements of the intended end users. Testing included simulated use evaluations performed by representative end users in addition to benchtop testing.

The following benchtop verification and validation testing was performed following internal test protocols:

- Needle guide dimensions
- Needle insertion force and damage during needle insertion
- Needle angulation accuracy
- Needle tip depth accuracy
- Needle guide attachment / removal force
- Sterile barrier integrity
- Packaging integrity
- Elastic bands holding force
- Needle gate pinch force
- Elastic bands attachment durability
- Imaging quality following administration of the needle guide and probe cover
- Probe midline needle insertion
- Material dimensions
- Packaging configuration

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
- Verification and Validation
- Safety compliance verification

The following guidance documents and standards were used to determine appropriate methods for evaluating the performance of the device:

- *AAMI / ANSI / ISO 10993-5:2009/(R)2014*, Biological Evaluation Of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity
- *AAMI / ANSI ST72:2019*, Bacterial Endotoxins - Test Methods, Routine Monitoring, And Alternatives To Batch Testing
- *ASTM D4332-14*, Standard Practice For Conditioning Containers, Packages, Or Packaging Components For Testing
- *ASTM F1980-16*, Standard Guide For Accelerated *Aging Of Sterile Barrier Systems For Medical Devices*
- *ASTM F756*, Standard Practice for Assessment of Hemolytic Properties of Materials
- *ISO 10993-1:2018*, Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing
- *ISO 10993-4:*2017, Biological Evaluation of Medical Devices – *Part 4*: Selection of tests for interactions with blood

- *ISO 10993-7:2008*, Biological Evaluation of Medical Devices - Part 7: Ethylene Oxide Sterilization Residuals
- *ISO 10993-10:2021*, Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization
- *ISO 10993-11:2017*, Biological Evaluation Of Medical Devices - Part 11: Tests For Systemic Toxicity
- *ISO 10993-12:2021*, Biological Evaluation Of Medical Devices - Part 12: Sample Preparation And Reference Materials
- *ISO 11135: 2014*, Sterilization of healthcare products - Ethylene Oxide- Requirements For Development, Validation And Routine Control Of A Sterilization
- ISO 11607-1:2019, Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems, Amendment 1: Application of risk management 2023
- ISO 11607-2:2019, Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes, Amendment 1: Application of risk management 2023
- FDA-2013-D-0305, Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process", Guidance for Industry and Food and Drug Administration Staff, 09/2023.

Summary of Clinical Tests:

The subject of this premarket submission, Accuro® 3S Needle Guide Kit, did not require clinical studies to support the determination of substantial equivalence.

Conclusion:

Accuro® 3S Needle Guide Kit exhibits similar characteristics and indications for use as legally marketed predicate and reference devices and testing demonstrates substantially equivalent performance. Therefore, Rivanna Medical considers Accuro® 3S Needle Guide Kit as substantially equivalent.