



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

July 24, 2026

Re: K261014
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: June 26, 2026
Received: June 26, 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 13:17:57 -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

510(k) Number (if known)

K261014

Device Name

Accuro® 3S Needle Guide Kit

Indications for Use (Describe)

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.

The SafeTrack™ magnet is detected by magnetic sensors to provide visual guidance for tracking the position of a needle with respect to ultrasound image data.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary- K261014

K261014 510(k) Summary

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

Date: March 27th, 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® 3S Needle Guide Kit

Common Name: Transducer, Ultrasonic, Diagnostic
Device Class: Class II
Product Codes: Diagnostic Ultrasound Transducer, 21 CFR 892.1570, 90-ITX

Legally Marketed Predicate Device:

Primary Predicate Device: K250469 Accuro® 3S Needle Guide Kit
Common/Usual Name: Transducer, Ultrasonic, Diagnostic
Classification Name: Class II
Product Code: Diagnostic Ultrasound Transducer, 21 CFR 892.1570, 90-ITX

Reference Device: K142445 Pinpoint™ GT Safety Introducer Needle
Common/Usual Name: Catheter Introducer
Classification Name: Class II
Product Code: Introducer, Catheter, 21 CFR 870.1340, DYB

Device Description:

The Accuro 3S Needle Guide Kit is designed for use with compatible ultrasound equipment, including the Accuro 3S diagnostic ultrasound imaging system. 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, a patient drape with two integrated probe elastic bands, and a needle with the integrated SafeTrack™ magnet.



The kit components are assembled into a sterilized CSR Wrap then packaged in a sterile tray. The final kit is sterilized under ethylene oxide.

These Accuro® 3S Needle Guide Kit components may be packaged together or combined separately with other sterile FDA-cleared single-use products.

Intended Use/Indications for Use:

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 contaminant.

The SafeTrack™ magnet is detected by magnetic sensors to provide visual guidance for tracking the position of a needle with respect to ultrasound image data.

Comparison to Predicate Device(s):

	Accuro® 3S Needle Guide Kit	Accuro® 3S Needle Guide Kit [K250469]	Pinpoint™ GT Safety Introducer Needle [K142445]
Trade Name	Accuro® 3S Needle Guide Kit	Accuro® 3S Needle Guide Kit	Pinpoint™ GT Safety Introducer Needle
FDA Classification Regulation	21 CFR 892.1570	21 CFR 892.1570	21 CFR 870.1340
FDA Product Code	ITX	ITX	DYB
US Classification	Class II	Class II	Class II
Type of device	Diagnostic Ultrasound Transducer	Diagnostic Ultrasound Transducer	Catheter Introducer
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	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	The Pinpoint™ GT Safety Introducer Needle is intended for patients requiring percutaneous access to place a guidewire for subsequent placement of catheters or other medical procedures requiring introducer needle access. The Pinpoint™ GT Safety Introducer Needle may be used in any appropriate patient population.



	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 contaminant. The SafeTrack™ magnet is detected by magnetic sensors to provide visual guidance for tracking the position of a needle with respect to ultrasound image data.	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 contaminant.	
Intended User	Qualified and trained healthcare professional	Qualified and trained healthcare professional	Qualified and trained healthcare professional
Prescription Use	Yes	Yes	Yes
Use Environment	Hospital, clinic	Hospital, clinic	Hospital, clinic
Biocompatible patient contact surface	Yes	Yes	Yes
Sterilization Method	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide
Disposition	Disposable	Disposable	Disposable
Contents	- Needle Guide - Conductive Ultrasound Gel - Probe Cover - Elastic Bands - Patient Drape - Needle with integrated SafeTrack™ Magnet	- Needle Guide - Conductive Ultrasound Gel - Probe Cover - Elastic Bands - Patient Drape	Needle with integrated magnet

Accuro® 3S Needle Guide Kit is substantially equivalent to the predicate device (K250469). The Accuro® 3S Needle Guide Kit indications for use is similar to the primary predicate device, Accuro® 3S Needle Guide Kit (K250469) and the reference device, Pinpoint™ GT Safety Introducer Needle (K142445). Both the subject device and the primary predicate device, Accuro® 3S Needle Guide Kit,



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. The subject device and the predicate also both have the patient drape with bands that support the needle guide positioning. The subject, primary predicate, and reference devices are prescription use and intended for the same use environments.

The key difference between the subject and primary predicate device is the inclusion of the previously 510(k) cleared needle with the SafeTrack™ magnet preassembled onto the needle. The magnet is integrated onto the needle hub and does not come in direct contact with the patient. The intended function of the SafeTrack™ magnet is to emit a magnetic field detectable by the magnetic sensors in the compatible Accuro® 3S diagnostic ultrasound imaging system probe to display the needle location. The new addition of the needle with the integrated SafeTrack™ magnet is similar to the reference device, Pinpoint™ GT Safety Introducer Needle, as both needles have a magnetic source intended to be detectable by their respective compatible ultrasound system probes, to display an indicator of the needle. The difference between the subject device and the Pinpoint™ GT Safety Introducer Needle is that the subject needle has a magnet attached onto the needle hub and the reference needle has a magnet integrated into the needle hub itself. 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 the needle with the SafeTrack™ magnet. 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
- *ISO 10993-1:2018*, Biological Evaluation of Medical Devices; Part 1 –Evaluation and Testing
- *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 the same characteristics and indications for use as legally marketed predicate and reference devices. Conclusions drawn from performance tests demonstrate substantial equivalence (SE). Therefore, Rivanna Medical considers Accuro® 3S Needle Guide Kit as substantially equivalent.