Accurate Access, LLC
% Sam Murray
Head of Regulatory and Quality
PRIA Healthcare Management, LLC
30 Batterson Park Rd.
Suite 120
Farmington, Connecticut 06032

July 27, 2026

Re: K262474
Trade/Device Name: ND Needle Guidance System
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic Ultrasonic Transducer
Regulatory Class: Class II
Product Code: ITX
Dated: July 17, 2026
Received: July 17, 2026

Dear Sam Murray:

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: 2026.07.27 16:42:21 -04'00' For

Yanna Kang, Ph.D.
Assistant Director
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.	K262474

Please provide the device trade name(s).

ND Needle Guidance System

Please provide your Indications for Use below.

The ND® Needle Guidance System is indicated for use in ultrasound-guided procedures where precise placement of common interventional devices is required, such as for vascular access.

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)

510(k) SUMMARY

K262474

CONTACT INFORMATION

Submitter and Address	Accurate Access, LLC 3951 E. Paradise View Dr. Paradise Valley, AZ 85253 480-662-0722
Contact Person	Nabil Dib, MD Interventional Cardiologist / Co-Manager ndib@isctr.org
Date Summary was Prepared	January 26, 2026

DEVICE NAME

Tradename	ND® Needle Guidance System
Common / Usual Name	Diagnostic Ultrasonic Transducer
Product Code	ITX
Regulation Number	892.1570
Regulatory Class	Class II

PREDICATE DEVICES

K160806	CIVCO Medical Instruments	Verza Guidance System
K093713	CIVCO Medical Instruments	AccuSITE Needle Guides

INDICATIONS for USE

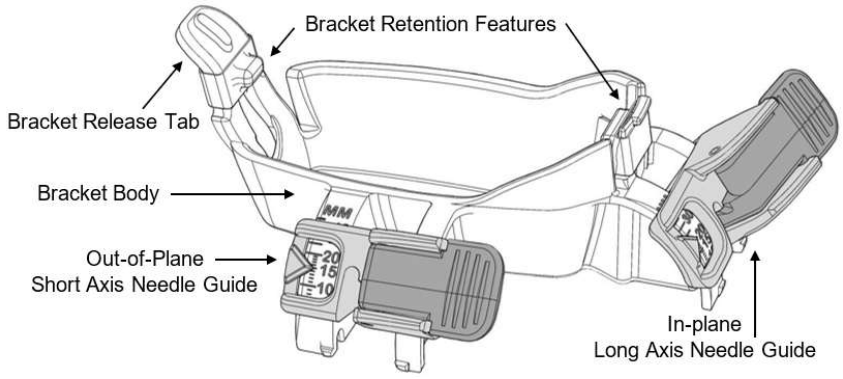
The ND® Needle Guidance System is indicated for use in ultrasound-guided procedures where precise placement of common interventional devices is required, such as for vascular access.

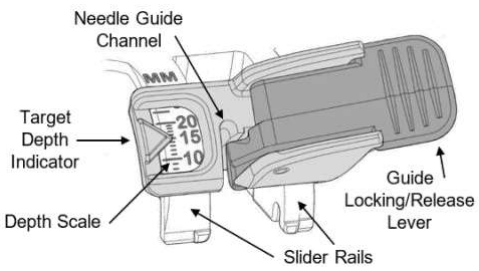
DEVICE DESCRIPTION

The ND Needle Guidance System is a sterile, single use device consisting of a molded bracket and two interchangeable needle guide configurations: in-plane and out-of-plane). The device mounts securely onto a commercially available ultrasound (US) probe to facilitate percutaneous access to targeted anatomical structures during diagnostic or therapeutic procedures.

The ultrasound probe is prepared with a sterile cover and allows real-time visualization while the ND Needle Guidance System provides mechanical stability and directional alignment for the needle/instrument to be inserted. The device provides an adjustable insertion depth range for both in-plane and out-of-plane configurations. Once needle or instrument placement is achieved, the guide's release mechanism enables removal of the guidance system without disturbing the position of the inserted device.

Bracket **Needle Guide**

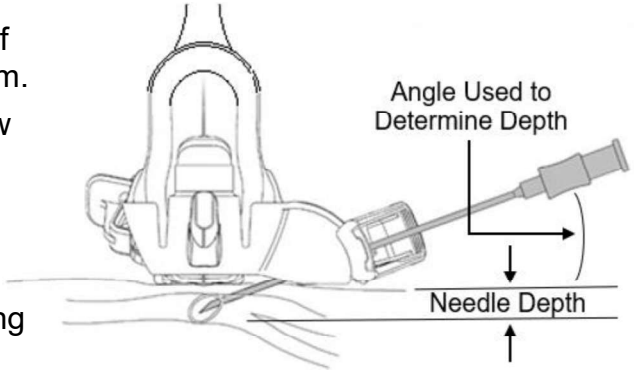




The ND Needle Guidance System is a molded plastic device consisting of components designed to allow it to be securely attached to an ultrasound probe. The device includes two (2) adjustable needle guides, one in the in-plane and one in the out-of-plane of ultrasound field view.

The in-plane needle guide provides a depth range of 10-35 mm and out-of-plane guide allows for 5-40 mm.

The device uses simple geometric principles to allow the desired depth to be selected via a calculated angular translation based on the ultrasound vessel depth measurement.



Once the target access has been achieved, the device is removed from the needle/instrument leaving it fixed in the targeted location to continue with the intended interventional procedure.

COMPARISON OF DEVICE CHARACTERISTICS

A comparison of the Indications for Use and technological features of the predicate and subject devices is provided in the table below and on the next page.

SPECIFICATION	SUBJECT DEVICE	PRIMARY PREDICATE DEVICE	SECOND PREDICATE DEVICE
510(k)	K000000 TBD	K160806	K093713
SPONSOR	Accurate Access	CIVCO Medical Instruments	CIVCO Medical Instruments
DEVICE	ND Needle Guidance System	Verza Needle Guidance System	AccuSITE US Needle Guides
INDICATION for USE	The ND Needle Guidance System is indicated for use where precise placement of a needle/instrument is needed for vascular access, tissue biopsy, fluid aspiration, or other treatment. The needle guidance system is affixed to a diagnostic ultrasound probe which provides visualization and guidance during insertion.	The system provides guidance for precise instrument placement of common interventional devices by positioning the device relative to the ultrasound transducer and the resulting image during a diagnostic or therapeutic procedure. This guidance system is intended for use with pediatric and adult patients.	The guidance system is intended for directing instruments such as catheters, electrodes and needles into a targeted anatomical location of a patient relative to the imaging instrument for percutaneous procedures. Prior to use healthcare workers should be trained in ultrasonography. • Vascular Access • Regional Anesthesia
REGULATORY	ITX | 892.1570	SAME	SAME

Discussion of Similarities and Differences

The principles of operation associated with the ND Needle Guidance System are the same for the predicate devices as well as other similar devices on the market for ultrasound guided access. Although other systems may use various methods to provide and secure the specific targeted depth selection (whether in-plane of out-of-plane), all are based on the same principle of achieving a desired depth by translating the associated access angle under ultrasound visualization.

Bracket + Needle Guide	The bracket is attached to a compatible OEM ultrasound transducer; the needle Guide is connected to the bracket.
Depth/Angle Selection	The subject and predicate devices all allow for depth/angle selection.
Needle Release	The subject and predicate devices all allow for the needle or instrument to be freely released from the guide channel.
In-Plane / Out-of-Plane	Only Subject device has both configurations in a single device.

PERFORMANCE DATA

Summary of Non-Clinical Testing

The ND Needle Guidance System was tested to and complies with applicable voluntary standards. The needle guide was tested to assure that the device meets its design specifications. Testing and results are summarized below.

Design Verification Testing

- Depth Scale Legibility
- Needle Fit Testing
- Slide Resistance Testing
- Probe Cover Durability
- Cycle Testing = Bracket Snapping on Probe + Lever Lock Testing

All acceptance criteria were met demonstrating that the ND Needle Guidance System meets the specified design input requirements.

Performance Testing

To cover a wide range of target vessel depths and device settings, testing of the ND Needle Guidance System was performed on 4 use configurations:

- 10 mm / Long Axis
- 35 mm / Long Axis
- 5 mm / Short Axis
- 40 mm / Short Axis

For Needle Centerline Testing and Needle Depth Accuracy Testing, all samples were within the acceptance criteria.

Biocompatibility

Biocompatibility testing was performed as summarized below.

#	BIOCOMPATIBILITY TEST	STANDARD	RESULTS
1	Cytotoxicity	ISO 10993-5	The ND Needle Guidance System passed all biocompatibility testing.
2	Sensitization	ISO 10993-10	
3	Irritation - Intracutaneous Injection	ISO 10993-23	
4	Acute Systemic Toxicity	ISO 10993-11	
5	Material Mediated Rabbit Pyrogen		
6	Hemolysis	ASTM F756	

Sterility Validation

Ethylene oxide (EtO) sterilization was validated achieving a sterility assurance level (SAL) of at least $1x10^{-6}$ in accordance with ANSI/AAMI/ISO 11135.

Shelf Life

Shelf life was validated with accelerated aging testing of 1 year per ISO 11607-1/-2.

Transportation Testing

The ND Needle Guidance System passed all transportation and package integrity testing per ASTM D4169/D4332/F1929/F2096/F88/F1886.

Usability Testing

During design and prototype development, a Formative Usability Evaluation was performed which included comprehensive design evaluations to assess the device's safety and performance. Results of usability testing confirmed that there were no critical tasks associated with use of the device with the testing demonstrating acceptable performance and user interaction per IEC 62366. Risk assessment documentation identified no critical tasks within the device workflow and all residual risks were deemed acceptable.

Phantom Testing

The ND Needle Guidance System was tested using a commercial phantom which included several "vessels" at anatomical depths, thus simulating conditions of normal clinical use. N=8 procedures were performed in the ultrasound phantom simulator including short and long axis testing. All acceptance criteria were met providing additional evidence of device performance.

Animal Study

An acute animal study was performed on a single pig (N=1). The purpose of the study was to evaluate the ND Needle Guidance System in the acute porcine animal model by obtaining vascular access in femoral vessels to demonstrate that the device performs as intended under conditions of simulated human clinical use.

Device performance was assessed by determining whether using the device resulted in successful puncture of the target vessel. These included the right and left femoral arteries and veins. Success was achieved at all 6 prespecified target sites.

The animal study also evaluated mechanical performance of the needle guidance system which was reported as passing for all endpoints. Inspection of the probe cover and the ultrasound probe did not reveal any evidence of damage.

There were no occurrences of adverse outcomes, nor reports of user difficulty.

In conclusion, the safety and performance data from the animal study provides strong support for 510(k) clearance of the ND Needle Guidance System.

CONCLUSION

Based on the results of the nonclinical and animal testing, the ND Needle Guidance System was demonstrated to be as safe as the predicates with performance data providing evidence supporting a determination of substantial equivalence.