April 23, 2025

Sonavex, Inc.
Ralph Del Negro
Manager of Product Strategy
2835 O'Donnell Street, Suite 200
Baltimore, Maryland 21224

Re: K243479
Trade/Device Name: EchoGuide (Version 1)
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic Pulsed Echo Imaging System
Regulatory Class: Class II
Product Code: IYO, ITX, LLZ
Dated: March 27, 2025
Received: March 28, 2025

Dear Ralph Del Negro:

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,

Gema Gonzalez -S

Maura Rooney
Assistant Director
DHT3A: Division of Renal, Gastrointestinal, Obesity, and Transplant Devices
OHT3: Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
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)*

K243479

Device Name

EchoGuide (Version 1)

Indications for Use *(Describe)*

EchoGuide is a vascular ultrasound imaging device meant to aid in identification of the cannulation site on the skin of mature arteriovenous fistulas/grafts (AVFs/AVGs) in adult patients by appropriately trained healthcare providers in clinical settings. This device is not meant to replace the current standard of care cannulation methods.

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) #: K243479

510(k) Summary

Prepared on: 2025-03-28

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Sonavex, Inc.
Applicant Address	2835 O'Donnell Street Suite 200 Baltimore MD 21224 United States
Applicant Contact Telephone	7324258549
Applicant Contact	Mr. Ralph Del Negro
Applicant Contact Email	rdelnegro@sonavex.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	EchoGuide (Version 1)
Common Name	Ultrasound System
Classification Name	Ultrasonic Pulsed Echo Imaging System
Regulation Number	892.1560
Product Code(s)	IYO, ITX, LLZ

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K140126	Sonic Window	IYO
K152554	Site-Rite 8	IYO
K190039	EchoSure	IYO

Device Description Summary

21 CFR 807.92(a)(4)

EchoGuide is a 3D automated ultrasound solution designed to provide the benefits of ultrasound for arteriovenous fistula/graft cannulation without the need for extensive training. EchoGuide uses a three-dimensional probe to acquire live coronal plane images, in addition to automating imaging settings, to allow users to quickly assess the position, trajectory, and size of an arteriovenous fistula/graft. Users can then mark the position and trajectory of the access on the patient's skin before removing the probe and proceeding with cannulation.

The EchoGuide probe houses a 2D array on a track. The piezoelectric material in the transducer is used as an ultrasound source to transmit sound waves into the body. Sound waves are reflected back to the transducer and converted to electrical signals that are processed. The transducer is a 52 mm linear (192 element) motorized probe capable of capturing a volume of data. The motorized probe collects a series of 2D images to capture a volume. Through image analysis and processing, the volumes are sliced to create live coronal plane renderings.

The ultrasound system has a laptop form factor, with a bottom touch screen for user interaction and an additional top screen for display. The ultrasound hardware, including transmitter and receiver, are all self-contained within the case. The ultrasound system interfaces with the probe through a port on the right side of the system.

The EchoGuide user interface defaults to a conventional 2D ultrasound image when the system powers on. Users can switch between this view, and the live coronal imaging via controls on the bottom screen of the ultrasound. Users can freeze the imaging and capture a

snapshot of the fistula/graft as well. The snapshot displays a static view of the fistula/graft in the coronal and transverse planes.

EchoGuide is intended to be used in a clinical setting at the point of hemodialysis care.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

EchoGuide is a vascular ultrasound imaging device meant to aid in identification of the cannulation site on the skin of mature arteriovenous fistulas/grafts (AVFs/AVGs) in adult patients by appropriately trained healthcare providers in clinical settings. This device is not meant to replace the current standard of care cannulation methods.

Indications for Use Comparison

21 CFR 807.92(a)(5)

EchoGuide and its predicate Sonic Window are both intended to visualize vessels in support of needle cannulation. There are minor differences in the indications.

Sonic Window is "intended for the visualization of vessels, and vascular access guidance of needles and catheters (Insertion of Peripheral Intravenous (PIV) Catheters as an example)" EchoGuide in intended for "identification of the cannulation site…of mature arteriovenous fistulas/grafts…"

Both devices are indicated for vascular imaging in support of cannulation and vessel access, with EchoGuide's indication specific to identifying cannulation locations of needles for arteriovenous fistulas/grafts. Sonic Window is intended to support access to peripheral vessels, of which arteriovenous fistula/grafts are a subset.

The differences in indication do not constitute a new intended use, because EchoGuide's indication is a more specific subset of Sonic Window's indication.

Technological Comparison

21 CFR 807.92(a)(6)

EchoGuide and its predicate Sonic Window utilize the same imaging modality to support their intended uses. Both devices support coronal plane imaging through an ultrasonic transducer, such that the piezoelectric material in the transducer is used as an ultrasound source to transmit sound waves into the body. Sound waves are reflected back to the transducer and converted to electrical signals that are processed to form coronal plane images.
There are two main technological differences between the devices. Sonic Window uses a matrix array to perform coronal plane imaging and is a fully integrated handheld device. EchoGuide uses a 2D linear array moved along a track to perform coronal plane imaging and has a laptop form factor and attached transducer.
The differences in form factor do not raise any new questions of safety or effectiveness. All ultrasound products must meet electromagnetic compatibility, acoustic output, biocompatibility, and imaging quality standards regardless of form factor.
The differences in arrays (matrix array vs. motorized linear array) do not raise any new questions of safety or effectiveness. Both devices use their arrays to capture a series of 2D images which are processed to form a coronal plane image. Although the method of collecting these images is different, the final output of the devices is the same.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

All necessary testing has been performed for EchoSure to assure substantial equivalence to the predicate device and to demonstrate that the device performs as intended. Internal verification and validation bench testing confirmed that the design outputs meet the design requirements and the device is suitable for its intended use.

The following standards based safety and performance testing was followed:
- ISO 10993-1:2009 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Test for in-vitro cytotoxicity
- ISO 10993-10:2020 Biological evaluation of medical devices - Part 10: Test for irritation and skin sensitization
- IEC 60601-2:2014+A1:2020 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- AAMI/ANSI ES 60601-1: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)
- IEC 62127-1:2022 Ultrasonics - Hydrophones-Part 1: Measurement and characterization of medical ultrasonic fields up to 40 MHz
- IEC 62359:2017 Ultrasonics - Fields characterization - Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields
- IEC 60601-2-37:2015 Particular Requirements for the Basic Safety and Essential Performance of Ultrasonic Medical Diagnostic and Monitoring Equipment
- Testing per FDA guidance Marketing Clearance of Diagnostic Ultrasound Systems and Transducers

Data from a non-significant risk observational study was used to confirm in vivo imaging adequacy of EchoGuide for the exam of hemodialysis accesses. The study was a prospective, single arm, non-randomized, observational study. The primary objective of the study was data collection. Images were collected on upper arm arteriovenous fistulae. This data confirms the imaging accuracy and quality of EchoGuide for in vivo use, supporting substantial equivalence.

EchoGuide is in conformance with the standards described above which demonstrate substantial equivalence to the predicate device Sonic Window. Bench testing confirms the device meets design requirements and can be used for its intended use. Clinical testing confirms the in vivo imaging adequacy of the device. EchoGuide met all specific criteria and any differences in intended use or technological characteristics between it and its predicate did not raise new questions of safety or performance. Testing therefore supports a finding of substantial equivalence.