March 10, 2026

FUJIFILM Sonosite, Inc.
% Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Dr. Suite #510k
Saint Paul, Minnesota 55114

Re: K260595
Trade/Device Name: Sonosite iLOOK Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: Class II
Product Code: IYN, ITX, IYO
Dated: February 23, 2026
Received: February 23, 2026

Dear Prithul Bom:

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 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 21 CFR 820.70) and document changes and approvals in the Medical Device File (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 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,

YANNA S. KANG -S

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

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K260595

Please provide the device trade name(s).

Sonosite iLOOK Ultrasound System

Please provide your Indications for Use below.

The Sonosite iLOOK Ultrasound System is a general purpose ultrasound system and non-continuous patient monitoring platform intended for use by qualified physicians and healthcare professionals for evaluation by ultrasound imaging or fluid flow analysis of the human body. Specific clinical applications and exam types include:
•Pediatric
•Peripheral vessel
•Needle Guidance

Modes of operation include: B Mode (B), Color Power Doppler, Color Velocity Doppler, Multi-beam imaging, and combined modes, including duplex imaging: B+C.

This device is indicated for Prescription Use Only.

The Sonosite iLOOK system is intended to be used in medical practices, clinical environments, including healthcare facilities, hospitals, clinics, and clinical point-of-care for diagnosis of patients.
The system includes a transducer and a display connected together wirelessly. The transducer is powered by battery, while the display is powered either by battery or by AC electrical power. The clinician is positioned next to the patient and places the transducer onto the patient's body where needed to obtain the desired ultrasound image.

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)

510(K) Summary K260595

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.

1) Submitter:

Manufacturer Name:	FUJIFILM SonoSite, Inc.
Address:	21919 30th Drive SE Bothell, WA 98021-3904
Corresponding Official:	Anoush Frankian Director, Regulatory Affairs
Email:	anoush.frankian@fujifilm.com
Telephone:	(425) 951-6824
Facsimile	(425) 951-1201
Date prepared:	February 6, 2026
Alternate Contact:	Abirami Krishnamurthi Regulatory Affairs Specialist abirami.krishnamurthi@fujifilm.com
Telephone:	(425) 951-6824
Facsimile:	(425) 951-1201

2) Device

Trade Name:	Sonosite iLOOK Ultrasound System
Common Name:	Diagnostic Ultrasound System and Transducers with Accessories
Regulation Name:	Ultrasonic Pulsed Doppler Imaging System Ultrasonic Pulsed Echo Imaging System Diagnostic Ultrasound Transducer
Regulation Number:	892.1550 892.1560 892.1570
Primary Product Code:	IYN

Secondary Product Codes:	IYO ITX
Device Class:	Class II
Classification Panel:	Radiology

3) Predicate Device:

Primary Predicate: Sonosite iViz Ultrasound System (K180704)

Regulation Name: Ultrasonic Pulsed Doppler Imaging System
Ultrasonic Pulsed Echo Imaging System
Diagnostic Ultrasound Transducer

Regulation Number: 892.1550
892.1560
892.1570

Primary Product Code: IYN
Secondary Product Code: IYO, ITX
Device Class: II
Classification Panel: Radiology

Reference Device: Vscan Air (K250087)

Regulation Name: Ultrasonic Pulsed Doppler Imaging System
Ultrasonic Pulsed Echo Imaging System
Diagnostic Ultrasound Transducer

Regulation Number: 892.1550
892.1560
892.1570

Primary Product Code: IYN
Secondary Product Code: IYO, ITX
Device Class: II
Classification Panel: Radiology

4) Device Description:

The Sonosite iLOOK Ultrasound System is a fully featured, general-purpose, software- controlled diagnostic ultrasound system utilizing an all-digital architecture. The system is a portable ultrasound device consisting of a display, adjustment handle, wireless L15-5 linear ultrasound transducer, and a transducer holder with a built-in wireless charger.

The system is designed to acquire and display high-resolution, real-time ultrasound data in 2D, Color Power Doppler (CPD), Color Velocity Doppler (CVD), or a combination of these modes. It provides measurement capabilities for anatomical structures and pediatric biometry, offering information for clinical diagnostic purposes.

The system includes a variety of accessories, including an optional stand. Additionally, it features Digital Imaging and Communications in Medicine (DICOM) capabilities, along with general computer communication functionalities, including wireless networking. These capabilities enable the acceptance, transfer, display, storage, and digital processing of ultrasound images and loops.

The system features a single USB port, allowing the use of compatible storage devices, such as memory sticks and hard drives. An AC adapter is included in the stand module, enabling manual connection to AC power.

Intended Use/Indications for Use:

The Sonosite iLOOK Ultrasound System is a general-purpose ultrasound system and non-continuous patient monitoring platform intended for use by qualified physicians and healthcare professionals for evaluation by ultrasound imaging or fluid flow analysis of the human body. Specific clinical applications and exam types include:

- Pediatric
- Peripheral vessel
- Needle Guidance

Modes of operation include: B Mode (B), Color Power Doppler, Color Velocity Doppler, Multi-beam imaging, and combined modes, including duplex imaging: B+C.

This device is indicated for Prescription Use Only.

The Sonosite iLOOK system is intended to be used in medical practices, clinical environments, including healthcare facilities, hospitals, clinics, and clinical point-of-care for diagnosis of patients. The system includes a transducer and a display connected together wirelessly. The transducer is powered by battery, while the display is powered either by battery or by AC electrical power. The clinician is positioned next to the patient and places the transducer onto the patient’s body where needed to obtain the desired ultrasound image.

5) Technological Characteristics:

The Sonosite iLOOK Ultrasound System, subject device of this submission, is equivalent to the previously cleared primary predicate Sonosite iViz Ultrasound System (K180704) and the reference device, Vscan Air (K250087) in terms of both the intended use and technological characteristics. The Sonosite iLOOK (subject device) uses the same fundamental scientific technology as the primary predicate device.

Feature	Sonosite iLOOK Ultrasound System (This submission)	Sonosite iViz Ultrasound System (K180704)- Primary Predicate	VScan Air (K250087)- Reference	Evaluation of Differences
Intended Use	Diagnostic ultrasound imaging or fluid flow analysis of the human body.	Diagnostic ultrasound imaging or fluid flow analysis of the human body.	Diagnostic ultrasound examinations, image guidance and for measurements of anatomical structures and fluid.	Same as the primary predicate Sonosite iViz Ultrasound System (K180704).
Indications for Use	Pediatric Peripheral vessel Needle guidance	Fetal – OB/GYN Abdominal Pediatric Small Organ (breast, thyroid, testicles, prostate) Musculoskeletal (Conventional) Musculoskeletal (Superficial) Cardiac Adult Cardiac Pediatric Peripheral vessel Ophthalmic	Vascular/ peripheral vascular musculoskeletal (conventional and superficial) small organs thoracic/lung ophthalmic pediatric neonatal cephalic interventional guidance (includes free-hand needle/ catheter placement, fluid drainage, nerve block, vascular access and biopsy)	Same. The indications for use include the subset of indications previously cleared on the primary predicate, Sonosite iViz Ultrasound system (K180704) and the reference device, Vscan Air (K250087).
Transducer Types	Linear Array	Curved Array Linear Array Phased Array	Linear array Sector array	Same. Sonosite iLOOK Ultrasound System include the subset of the transducer types that were previously cleared on the primary predicate Sonosite iViz Ultrasound System (K180704) and reference device Vscan Air (K250087).

Transducer Frequency	5- 15 MHz	6-13 MHz	3 – 12 MHz	The transducer frequency range is similar to both primary predicate Sonosite iViz Ultrasound System (K180704) and reference device Vscan Air (K250087). iLOOK L15-5 and iViz L25v are both linear transducers, while iLOOK L15-5 covers a wider bandwidth and higher frequency.
Global Maximum Outputs/Worst Case Setting	Ispta.3=138.41mW/cm2 (Color, ROI Deep) TI= 0.42 MI =0.80 Ipa.3@MI Max: 268.8 mW/cm^2	Ispta.3= 47.7 mW/cm^2 TI Value: 0.42 MI: 0.86 $I_{pa.3}$@MI Max: 272 W/cm^2	MI <1.9 Ispta<720 mW/cm^2	Acoustic output is within the FDA established limits.
Acoustic Output Display & FDA Limits	No output display because MI<1.0, TI<1.0	MI and TI are displayed	MI and TI values are displayed on the scanning screen.	MI and TI values are less than 1.0. IEC 60601-2-37 Ed 3.0 section 201.12.4.2 "Indication relevant to safety" b) and c) which states no display is required if you meet the criteria.
Modes of Operation	2D (B-mode Grayscale Imaging) Color Velocity Doppler Color Power Doppler Combination modes (color mode is combined with 2D)	B-mode Grayscale Imaging Tissue Harmonic Imaging M-mode Color M-Mode Color Power Doppler Zoom Combination Modes SonoHD3 Noise Reduction	B-mode Color Doppler M-mode PW	Modes of operations include the subset of the previously cleared modes on the primary predicate (K180704).

		Velocity Color Doppler		
DICOM	DICOM 3.0 Image and Multi-frame Image Storage; Modality Worklist; BCP 195 RFC 8996 TLS Secure Transport Connection	DICOM 3.0 Image, Multi-frame Image, Secondary Capture, and Basic Text Structured Report Storage; Modality Worklist; USB Media Storage	DICOM 3.0 Modality Worklist Server DICOM Image Server Network Shared Folder DICOM Web Server	Same as the primary predicate (K180704)
#Transmit Channels	64	64	No information available publicly	Same as the primary predicate (K180704)
#Receive Channels	64	64 digital channels using Synthetic Aperture	No information available publicly	Same as the primary predicate (K180704)
Patient Contact Materials	Transducers: m-PPE SEBS Elastomer Silicone rubber compounds (Shin-Etsu KE-752U) Silicone rubber compounds (Shin-Etsu KE-45T)	Transducers: Polysulfone UDEL P1700 Poly-Vinyl-Chloride (PVC) Silicone Rubber	No information available publicly	The materials introduced in this submission have passed biocompatibility testing in accordance with ISO 10993-1, and the results are provided in the biocompatibility section of the eSTAR.

DICOM	DICOM PS3.15	NEMA PS3.15	DICOM PS3.15	Same

System characteristics	Tablet dimensions: 10.1 inches 1920x1200 pixels LCD Operating system: Android iLOOK ultrasound software running as an “app” on tablet System operates via battery Wireless 802.11 support for image transfer Transducer dimensions: L15-5 transducer • Length: 151 mm (5.94 in) • Width: 56.5 mm (2.22 in) • Depth: 29.5 mm (1.16 in) • Weight: 170 g (6 oz) Stand • Depth: 54.4 cm (21.42 in) wheels turned in; 59.6 cm (23.46 in) wheels turned out • Width: 49.2 cm (19.37 in) wheels	Tablet dimensions: 7” inches 1920 x 1200 pixels LCD Operating system: Android iViz ultrasound software running as an “app” on tablet System operates via battery Wireless 802.11 support for image transfer and over the-air (OTA) software updates. Dimensions: System (without the case) • Length: 7.21 in. (183.1 mm) • Width: 4.59 in. (116.5 mm) • Height: 1.06 in (26.9 mm) System (with the case) • Length: 9.5 in.	Transducer S probe dimensions: • Dimension: 141 x 67 x 33 mm (length, width, height) • Weight: 218 +/- 3g Operating system options: - Android phones and tablets with OS version 11, 12 or 13, device with 0x64 ARM based CPU architecture and 64-bit Kernel, Android open GL ES 3.0, and compatibility with Google Play store - iPad and iPhone devices with iOS 14, 15 or 16 • Screen requirements - Size: from 5 to 20 inches - 960 x 640 (or 640 x 960) pixel or more	Same as the primary predicate, iViz (K180704), iLOOK is a tablet with a 10.1 inches display that runs on an Android Operating system and a transducer connected wirelessly, which is similar to the reference device Vscan Air (K250087).

	turned in; 57.7 cm (22.72 in) wheels turned out • Height: 129.4 cm (50.94 in) maximum, 165.1 cm (65 in) minimum • Weight: 15.0 kg (33.07 lbs) • Storage bin capacity: 3 kg (6.6 lbs) • Tray capacity: 3 kg (6.6 lbs) • Total stand weight with system and peripherals: 17.65 kg (38.91 lbs) maximum. System (display, stand mount, and transducer holder) • Width: 36.9 cm (14.53 in) • Height: 23.6 cm (9.29 in) • Depth: 5.2 cm (2.05 in) • Diagonal: 25.65 cm (10.1 in) • Resolution: 1920 x 1200 px • Weight: 1.85 kg (4.08 lbs)	(241.3 mm) • Width: 4.8 in. (123.0 mm) • Height: 1.12 in. (28.6 mm) Display • Length: 6.37 in. (161.87 mm) • Width: 4.11 in. (104.52 mm) • Diagonal: 7.0 in. (177.8 mm)		

	Total system (system plus stand) • Depth: 54- 70 cm (21.26- 27.56 in) • Width: 48.5- 58 cm (19.09- 22.83 in) • Height: 140- 167 cm (55.12- 65.75 in)			

510k Track	Track 3	Track 3	Track 3	Same

6) Determination of Substantial Equivalence:

Summary of Technological Comparison to Predicate Devices:

The Sonosite iLOOK Ultrasound System, subject device of this submission, is an enhanced implementation of previous FDA cleared primary predicate device Sonosite iViz Ultrasound System (K180704) and reference device, Vscan Air (K250087).

The primary function of Sonosite iLOOK Ultrasound System (this submission) and the predicate device is diagnostic ultrasound imaging or fluid flow analysis of the human body. The Sonosite iLOOK Ultrasound System employs the same fundamental scientific characteristics as the currently marketed primary predicate and reference devices. The Sonosite iLOOK Ultrasound System and both primary predicate (K180704) and reference device (K250087) share indications for use, share modes of operation and have biosafety equivalence.

The following lists an overview of differences between the proposed subject device (Sonosite iLOOK Ultrasound System) and its predicates.

- The Sonosite iLOOK Ultrasound System offers an all-touch display that is similar to the primary predicate device iViz (K180704) with a slightly larger size on the tablet of 10.1 inches compared to the 7 inches offered on the primary predicate iViz (K180704). Like the primary predicate (K180704), the iLOOK Ultrasound System operates via battery or AC electric power. The tablet is offered with a stand.
- The Sonosite iLOOK Ultrasound System utilizes wireless connectivity for its wireless ultrasound transducer, which is the same as the reference device Vscan Air's (K250087) SL probe that has wireless connectivity capability.
- The Sonosite iLOOK Ultrasound System also includes the addition of Needle Guidance as an indication, which is the same as the Needle Guidance indication offered on the reference device Vscan Air (K250087).
- The Sonosite iLOOK Ultrasound System uses advanced image processing (CViz) that is available on most cleared Sonosite products and is derived from the SonoHD3 image processing feature that is available on the primary predicate Sonosite iViz Ultrasound System (K180704).

7) Summary of Non-Clinical Tests:

The Sonosite iLOOK Ultrasound System, a fully featured, general-purpose, software controlled diagnostic ultrasound system, utilizes an all-digital architecture and a wireless transducer (L15-5). It is a portable ultrasound device consisting of a display, adjustment handle, and a transducer holder with a built-in wireless charger. The Sonosite iLOOK Ultrasound System has been evaluated for electrical, thermal, mechanical, and EMC safety. Additionally, cleaning/disinfection, biocompatibility, and acoustic output have been evaluated for Sonosite iLOOK, and the device has been found to conform to applicable medical device safety standards.

Assurance of quality was established by employing the following elements of product development: Design Phase Reviews, Risk Assessment, Requirements Development, System and Software Verification, Hardware Verification, Safety Compliance Verification, and Clinical Validation. All patient contact materials are biocompatible.

The Sonosite iLOOK Ultrasound System is designed to comply with the following FDA recognized standards.

Reference No.	Recognition No.	Title
ISO 10993-1	2-258	ISO 10993-1:2018, Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
IEC 60601-1	19-46	AAMI / ANSI ES60601- 1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)
IEC 60601-1-2	19-36	ANSI AAMI IEC 60601-1-2:2014 Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance -- Collateral Standard: Electromagnetic disturbances -- Requirements and tests
IEC 60601-1-6	5-132	IEC 60601-1-6 Edition 3.1 2013-10 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
IEC 60601-2-37	12-293	IEC Edition 3.0 2024 Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
IEC 62304	13-79	ANSI AAMI IEC 62304:2006/A1:2016 Medical device software - Software life cycle processes [Including Amendment 1 (2016)
ISO 14971	5-125	ANSI AAMI ISO 14971:2019 Medical devices - Application of risk management to medical devices
IEC 62359	12-316	IEC 62359 Edition 2.1 2017-09 CONSOLIDATED VERSION - Ultrasonics - Field characterization - Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields

8) Summary of Clinical Tests:

The Sonosite iLOOK Ultrasound System and transducers, subject of this submission, a fully featured, general-purpose, software controlled diagnostic ultrasound system, utilizes an all-digital architecture and a wireless transducer (L15-5). It is a portable ultrasound device consisting of a display, adjustment handle, and a transducer holder with a built-in wireless charger. The Sonosite iLOOK Ultrasound System did not require clinical studies to support the determination of substantial equivalence. The Sonosite iLOOK has been successfully tested in a clinical environment and the device performed as expected.

9) Conclusion:

Intended uses and other key features are consistent with traditional clinical practice and FDA guidance. The Sonosite iLOOK Ultrasound System and both predicate and reference devices conform to applicable electromedical device safety standards with compliance verified through independent evaluation. The Sonosite iLOOK Ultrasound System and both predicate and reference devices meet FDA requirements for Track 3 devices, share indications for use, have biosafety equivalence and are manufactured using the same ISO 13485 and 21 CFR 820 quality system. FUJIFILM SonoSite, Inc. believes that the Sonosite iLOOK Ultrasound System is substantially equivalent with regards to safety and effectiveness to the predicate devices.