



December 05, 2025

Sonoscape Medical Corp.
Toki Wu
Regulatory Affairs Director
Room 201 & 202, 12th Bldg, Shenzhen Software Park Phase II
1 Keji Middle 2nd Road, Yuehai Subdistrict, Nanshan District
Shenzhen, Guangdong 518057
CHINA

Re: K252498

Trade/Device Name: Digital Color Doppler Ultrasound System (X11 Exp/X11 Elite/X11 Pro/X11 Plus/X11 Super/X11 Senior/X11/E11/E11 Pro/E11 Plus/E11 Elite/X11 T/X11U/X11R/X11i/X11s/E11T/E11i/E11s/XR1/XR2/XR3/ER1/ER2/ER3/X10 Exp/X10 Elite/X10 Pro/X10 Plus/X10 Super/X10Senior/X10/X10T/ X10U/X10R/X10i/X10s/E10/E10 Pro/E10 Plus/E10T/E10i/E10s/SU11A EXP/SU11A PRO/SU11A AD/SU11A CU/SU11B EXP/SU11B PRO/SU11B AD/SU11B CU/SU11C EXP/SU11C PRO/SU11C AD/SU11C CU)

Regulation Number: 21 CFR 892.1550

Regulation Name: Ultrasonic Pulsed Doppler Imaging System

Regulatory Class: Class II

Product Code: IYN, IYO, ITX

Dated: November 10, 2025

Received: November 10, 2025

Dear Toki Wu:

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,

MARJAN NABILI -S 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

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

K252498

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Please provide the device trade name(s).

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Digital Color Doppler Ultrasound System (X11 Exp/X11 Elite/X11 Pro/X11 Plus/X11 Super/X11 Senior/X11/E11/E11 Pro/E11 Plus/E11 Elite/X11T/X11U/X11R/X11i/X11s/E11T/E11i/E11s/XR1/XR2/XR3/ER1/ER2/ER3/X10 Exp/X10 Elite/X10 Pro/X10 Plus/X10 Super/X10 Senior/X10/X10T/X10U/X10R/X10i/X10s/E10/E10 Pro/E10 Plus/E10T/E10i/E10s/SU11A EXP/SU11A PRO/SU11A AD/SU11A CU/SU11B EXP/SU11B PRO/SU11B AD/SU11B CU/SU11C EXP/SU11C PRO/SU11C AD/SU11C CU)

Please provide your Indications for Use below.

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The Digital Color Doppler Ultrasound System is a general-purpose ultrasonic imaging system intended for use by sufficiently trained healthcare professionals for ultrasound imaging, measurement, and analysis of the human body, which is intended to be used in a hospital or medical clinic.

The system is intended for use in the following clinical applications: Fetal, Abdominal, Pediatric, Small Organ (breast, testes, thyroid), Cephalic (neonatal and adult), Trans-rectal, Trans-vaginal, Peripheral Vascular, Cerebral Vascular, Musculo-skeletal (Conventional and Superficial), Cardiac (pediatric and adult), OB/Gyn and Urology.

Modes of operation include: B, M, PW Doppler, CW Doppler, Color Doppler, Color M Doppler, Power Doppler, Directional Power Doppler, Tissue Harmonic Imaging, Tissue Doppler Imaging, 3D/4D Imaging mode, Strain Elastography, Contrast imaging and Combined modes: B/M, B/PWD, B/THI, M/Color M, B/Color Doppler, B/Color Doppler/PWD, B/Power Doppler/PWD.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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Tab 052 510(k) Summary

K252498

This 510(k) Summary is being submitted in accordance with requirements of Title 21, CFR Section 807.92.

The assigned 510(k) Number: K252498

1. Date of Preparation: 11/10/2025

2. Sponsor Identification

SONOSCAPE MEDICAL CORP.

Room 201 & 202, 12th Building, Shenzhen Software Park Phase II, 1 Keji Middle 2nd Road, Yuehai Subdistrict, Nanshan District, Shenzhen, 518057, Guangdong, China.

Establishment Registration Number: 3004705634

Contact Person: Toki Wu

Position: Regulatory Affairs Director

Tel: +86-755-26722890

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3. Identification of Subject Device

Common Name: Diagnostic Ultrasound System and Transducers

Trade Name:

Digital Color Doppler Ultrasound System (X11 Exp/X11 Elite/X11 Pro/X11 Plus/X11 Super/X11 Senior/X11/E11/E11 Pro/E11 Plus/E11 Elite/X11T/X11U/X11R/X11i/X11s/E11T/E11i/E11s/XR1/XR2/XR3/ER1/ER2/ER3/X10 Exp/X10 Elite/X10 Pro/X10 Plus/X10 Super/X10 Senior/X10/X10T/X10U/X10R/X10i/X10s/E10/E10 Pro/E10 Plus/E10T/E10i/E10s/SU11A EXP/SU11A PRO/SU11A AD/SU11A CU/SU11B EXP/SU11B PRO/SU11B AD/SU11B CU/SU11C EXP/SU11C PRO/SU11C AD/SU11C CU)

Regulatory Information

	<u>CFR Number</u>	<u>Product Code</u>
Ultrasonic Pulsed Doppler Imaging System (Primary)	892.1550	90-IYN
Ultrasonic Pulsed Echo Imaging System	892.1560	90-IYO

Diagnostic Ultrasound Transducer

892.1570

90-ITX

Classification Panel: Radiology

Device Classification: II

Indication for Use:

The Digital Color Doppler Ultrasound System is a general-purpose ultrasonic imaging system intended for use by sufficiently trained healthcare professionals for ultrasound imaging, measurement, and analysis of the human body, which is intended to be used in a hospital or medical clinic.

The system is intended for use in the following clinical applications: Fetal, Abdominal, Pediatric, Small Organ (breast, testes, thyroid), Cephalic (neonatal and adult), Trans-rectal, Trans-vaginal, Peripheral Vascular, Cerebral Vascular, Musculo-skeletal (Conventional and Superficial), Cardiac (pediatric and adult), OB/Gyn and Urology.

Modes of operation include: B, M, PW Doppler, CW Doppler, Color Doppler, Color M Doppler, Power Doppler, Directional Power Doppler, Tissue Harmonic Imaging, Tissue Doppler Imaging, 3D/4D Imaging mode, Strain Elastography, Contrast imaging and Combined modes: B/M, B/PWD, B/THI, M/Color M, B/Color Doppler, B/Color Doppler/PWD, B/Power Doppler/PWD.

Device Description:

This X11 Exp/X11 Elite/X11 Pro/X11 Plus/X11 Super/X11 Senior/X11/E11/E11 Pro/E11 Plus/E11 Elite/X11T/X11U/X11R/X11i/X11s/E11T/E11i/E11s/XR1/XR2/XR3/ER1/ER2/ER3/X10 Exp/X10 Elite/X10 Pro/X10 Plus/X10 Super/X10 Senior/X10/X10T/X10U/X10R/X10i/X10s/E10/E10 Pro/E10 Plus/E10T/E10i/E10s/SU11A EXP/SU11A PRO/SU11A AD/SU11A CU/SU11B EXP/SU11B PRO/SU11B AD/SU11B CU/SU11C EXP/SU11C PRO/SU11C AD/SU11C CU Digital Color Doppler Ultrasound System (hereafter as “X11 Exp Series Digital Color Doppler Ultrasound System”) is an integrated preprogrammed color ultrasound imaging system, capable of producing high detail resolution intended for clinical diagnostic imaging applications.

The basic principle is that system transmits ultrasonic energy into patient body and implements post processing of received echoes to generate onscreen display of anatomic structures and fluid flow within the body.

This system is a Track 3 device that employs a wide array of probes that include linear array, convex array phased array and etc.

This system consists of a console with touch screen and keyboard control panel, power supply module, color LCD monitor and optional probes.

This system is a portable, general purpose, software controlled, color diagnostic ultrasound system. Its basic function is to acquire ultrasound data and to display the image in B-Mode (including Tissue Harmonic Image), M-Mode, TDI, Color-Flow Doppler, Pulsed Wave Doppler, Continued Wave Doppler and Power Doppler, or the combination of these modes, Elastography, contrast, 3D/4D.

4. Identification of Predicate Device

Type	Device	510 (k) Number	Manufacturer
1 Primary Predicate Device	S90 Exp Series Digital Color Doppler Ultrasound System	K222596	SonoScape Medical Corp.
2 Reference Device	P20 Elite Series Digital Color Doppler Ultrasound System	K221140	SonoScape Medical Corp.
3 Reference Device	Aplio i900/i800/i700/i600 Diagnostic Ultrasound System	K191467	Canon Medical Systems Corporation

5. Non-Clinical Test Conclusion

Non-clinical tests were conducted to evaluate for acoustic output, biocompatibility, reprocessing effectiveness as well as electrical, mechanical, thermal and electromagnetic compatibility safety, and has been found to comply with the applicable medical device safety standards. The X11 Exp Series Digital Color Doppler Ultrasound System has been designed and manufactured to meet the following standards.

AAMI/ANSI ES 60601-1, Medical Electrical Equipment- Part 1: General requirements for basic safety and essential performance [Edition 3.2, 2021];

IEC 60601-1-2, Medical electrical equipment - Part 1-2 General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests [Edition 4.1, 2020];

IEC 60601-2-37, Medical Electrical Equipment - Part 2-37: Particular requirements for basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment [Edition 2.1, 2015];

ISO 10993-1, Biological Evaluation of Medical Devices, Part 1: evaluation and testing within a risk management process [2018];

AIUM/NEMA UD 2, Acoustic output measurement standard for diagnostic ultrasound equipment [Revision 3, 2009].

6. Clinical Test Conclusion

No clinical study is included in this submission.

7. Comparison with Predicate Devices

The Subject device X11 Exp Series Digital Color Doppler Ultrasound System is comparable with and substantially equivalent to the predicate devices with regards to intended uses, imaging modes, acoustic output levels, probes and biopsy brackets supported, technical characteristics and features.

- The X11 Exp Series Digital Color Doppler Ultrasound System has the same intended use and imaging modes as the predicate device S90 Exp Series (K222596);

- The X11 Exp Series Digital Color Doppler Ultrasound System is designed in compliance with the FDA recognized electrical and physical safety standards, which are the same as the predicate device S90 Exp Series (K222596);
- The acoustic output levels of the X11 Exp Series Digital Color Doppler Ultrasound System are below the limits of FDA, which are the same as the predicate device S90 Exp Series (K222596);
- The probes and biopsy brackets supported in the X11 Exp Series Digital Color Doppler Ultrasound System have been mostly migrated from the predicate device S90 Exp Series (K222596) and P20 Elite Series (K221140); the new probes 22L-A and P4-12 are equivalent to the probes 18L-A and 8P1 respectively, which have been cleared with predicate device SonoScape S90 Series (K222596);
- The X11 Exp Series Digital Color Doppler Ultrasound System has the following new features, including SR Flow, Micro F, FHR, FreeVue, S-Live / S-Live Silhouette/ S-Live Contour, S-Depth, S-MSK, Auto Bladder, Auto IMT, Auto EF, Auto NT and Auto OB, which have been migrated from the predicate device S90 Exp Series (K222596) and P20 Elite Series (K221140);
- The X11 Exp Series Digital Color Doppler Ultrasound System has three new features (auto measurements), including Auto CV, Auto IVC and Auto VTI, which are equivalent to the corresponding manual measurements cleared in the predicate device S90 Exp Series (K222596).
- The X11 Exp Series Digital Color Doppler Ultrasound System add three new features, ATI, SonoFast and Auto hyd. & asc. The ATI feature is equivalent to the Attenuation Imaging (ATI) function cleared with reference device Aplio i900/i800 Diagnostic Ultrasound System (K191467). The SonoFast feature is the preset procedure or customized workflow. The Auto hyd. & asc. feature is equivalent to the basic manual measurement.

8. Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the subject device is as safe, as effective, and performs as well as the legally marketed predicate devices.