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

May 15, 2026

Re: K254028
Trade/Device Name: Digital Color Doppler Ultrasound System (Autra RS/ Autra 90/ Autra Senior/ Autra CV/ e-Autra/ Autra 75/ Autra 85W/ Autra 65/ Autra 55/ Autra 65i/ Autra 90 Elite/ Autra 85 Elite/ Autra 80 Elite/ Autra 75 Elite/ Autra 85 CV/ Autra 80W/ Autra 65 Elite/ Autra 55 Elite/ Autra 55i/ Autra 90 CV/ Autra 85/ Autra 80/ Autra 80 CV/ Autra 75 Pro/ Autra 75W/ Autra 70 Elite/ Autra 70/ Autra T)
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic Pulsed Doppler Imaging System
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: April 17, 2026
Received: April 17, 2026

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 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 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 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: 2026.05.15 15:28:32 -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

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.

510(k) Number *(if known)*
K254028

Device Name
Digital Color Doppler Ultrasound System (Autra RS/Autra 90/Autra Senior/Autra CV/e-Autra/Autra 75/Autra 85W/Autra 65/Autra 55/Autra 65i/Autra 90 Elite/Autra 85 Elite/Autra 80 Elite/Autra 75 Elite/Autra 85 CV/Autra 80W/Autra 65 Elite/Autra 55 Elite/Autra 55i/Autra 90 CV/Autra 85/Autra 80/Autra 80 CV/Autra 75 Pro/Autra 75W/Autra 70 Elite/Autra 70/Autra T)

Indications for Use *(Describe)*
The Autra RS Series Digital Color Doppler Ultrasound System is a general-purpose ultrasonic imaging system intended for use by qualified and appropriately 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, Shear Wave 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.

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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K254028

Tab 050 510(k) Summary

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

The assigned 510(k) Number: K254028

1. Date of Preparation: May 13, 2026

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
Fax: +86-755-26722850
Email: ra@sonoscape.net

3. Identification of Subject Device

Common Name: Diagnostic Ultrasound System and Transducers
Trade Name:
Digital Color Doppler Ultrasound System (Autra RS/Autra 90/Autra Senior/Autra CV/e-Autra/Autra 75/Autra 85W/Autra 65/Autra 55/Autra 65i/Autra 90 Elite/Autra 85 Elite/Autra 80 Elite/Autra 75 Elite/Autra 85 CV/Autra 80W/Autra 65 Elite/Autra 55 Elite/Autra 55i/Autra 90 CV/Autra 85/Autra 80/Autra 80 CV/Autra 75 Pro/Autra 75W/Autra 70 Elite/Autra 70/Autra T)

Regulatory Information

	CFR Number	Product Code
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 Autra RS Series Digital Color Doppler Ultrasound System is a general-purpose ultrasonic imaging system intended for use by qualified and appropriately 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, Shear Wave 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 Autra RS/Autra 90/Autra Senior/Autra CV/e-Autra/Autra 75/Autra 85W/Autra 65/Autra 55/Autra 65i/Autra 90 Elite/Autra 85 Elite/Autra 80 Elite/Autra 75 Elite/Autra 85 CV/Autra 80W/Autra 65 Elite/Autra 55 Elite/Autra 55i/Autra 90 CV/Autra 85/Autra 80/Autra 80 CV/Autra 75 Pro/Autra 75W/Autra 70 Elite/Autra 70/Autra T Digital Color Doppler Ultrasound System (hereafter as “Autra RS 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 mobile console with touch screen and keyboard control panel, power supply module, color LCD monitor and optional probes.

This system is a mobile, 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, Power Doppler and Directional Power Doppler Imaging, or the combination of these modes, contrast imaging, strain Elastography, shear Wave Elastography, SonoFusion, 3D/4D.

4. Identification of Predicate Device

Type	Manufacturer	Device	510 (k) Number
1 Primary Predicate Device	SonoScape Medical Corp.	S90 Exp Series Digital Color Doppler Ultrasound System	K222596
2 Reference Device	SonoScape Medical Corp.	P60 Series Digital Color Doppler Ultrasound System	K241949
3 Reference Device	SonoScape Medical Corp.	X11 Exp Series Digital Color Doppler Ultrasound System	K252498
4 Reference Device	SonoScape Medical Corp.	P50 Series Digital Color Doppler Ultrasound System	K170999
5 Reference Device	Shenzhen Mindray Bio-medical Electronics Co., LTD.	Resona A10S Diagnostic Ultrasound System	K242231

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 Autra RS Series 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 3.0, 2024];
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 Autra RS 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 Autra RS Series Digital Color Doppler Ultrasound System has the same intended use and imaging modes as the predicate device S90 Exp Series (K222596);
- The Autra RS 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 Autra RS 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 supported in the Autra RS Series Digital Color Doppler Ultrasound System have been mostly migrated from the predicate device S90 Exp Series (K222596), P60 Series (K241949) and X11 Exp Series (K252498); the new probes L3-18, xL3-18, C1-7, C1-7-M, xC1-7, VC2-10, S1-6, xS1-6, VE3-12, EC3-12 and ER4-13 are equivalent to the probes cleared with predicate device S90 Exp Series (K222596), P60 Series (K241949) and P50 Series (K170999);
- The biopsy brackets supported in the Autra RS Series Digital Color Doppler Ultrasound System have been mostly migrated from the predicate device S90 Exp Series (K222596); the new biopsy brackets NGBL3-18, NGBxL3-18, NGBxC1-7, NGBC1-7, NGBS1-6, NGBxS1-6, NGBP4-12, NGBVE3-12 and NGBEC3-12 are equivalent to the biopsy brackets cleared with predicate device S90 Exp Series (K222596).

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.