January 17, 2025

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

Re: K241949
Trade/Device Name: Digital Color Doppler Ultrasound System (P60 Series)
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic Pulsed Doppler Imaging System
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: December 16, 2024
Received: December 16, 2024

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,

YANNA S. KANG -S

Yanna Kang, Ph.D.
Assistant Director
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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)*

K241949

Device Name

Digital Color Doppler Ultrasound System (P60 Series)

Indications for Use *(Describe)*

The Digital Color Doppler Ultrasound System is a general-purpose ultrasonic imaging instrument intended for use by appropriately trained healthcare professionals in hospital for evaluation of Fetal, Abdominal, Pediatric, Small Organ (breast, testes, thyroid), Cephalic (neonatal and adult), Trans-rectal, Trans-vaginal, Peripheral Vascular, Cerebral Vascular, Musculoskeletal (Conventional and Superficial), Cardiac (pediatric and adult), Trans-esoph (Cardiac), Laparoscopic, 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.

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.

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: K241949

1. Date of Preparation: 11/25/2024

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

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3. Identification of Subject Device

Trade Name: P60 Series Digital Color Doppler Ultrasound System
Models: P60 Exp, P60 Pro, P60, P60 CV, P70T, P70S, P60S, P60 VO, P55, P55 Elite, P55S, P50T, P50 Elite, P50E, P40T, P40 Elite, P40E, P30T, P30 Elite, P30E, P25S, P22S, SonoStage M1
Common Name: Diagnostic Ultrasound System and Transducers

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 P60 Series Digital Color Doppler Ultrasound System is a general-purpose ultrasonic imaging instrument intended for use by appropriately trained healthcare professionals in hospital for evaluation of Fetal, Abdominal, Pediatric, Small Organ (breast, testes, thyroid), Cephalic (neonatal and adult), Trans-rectal, Trans-vaginal, Peripheral Vascular, Cerebral Vascular, Musculoskeletal (Conventional and Superficial), Cardiac (pediatric and adult), Trans-esoph (Cardiac), Laparoscopic, 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 SonoScape P60 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, Direction Power Doppler, or the combination of these modes, Compound, 3D/4D, Elastography and Contrast.

4. Identification of Predicate Device

Type	Device	510 (k) Number	Manufacturer
1) Primary Predicate Device	P60 Series Digital Color Doppler Ultrasound System	K171000	SonoScape Medical Corp.
2) Reference Device	S90 Exp Series Digital Color Doppler Ultrasound System	K222596	SonoScape Medical Corp.
3) Reference Device	P20 Elite Series Digital Color Doppler Ultrasound System	K221140	SonoScape Medical Corp.

5. Non-Clinical Test Conclusion

Non clinical tests were conducted to evaluate for acoustic output, biocompatibility as well as electrical, mechanical, thermal and electromagnetic compatibility safety, and has been found to comply with the applicable medical device safety standards. The P60 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 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].

The Summary of performance test for the new feature (S-Fetus^{AI})

1) Standalone Performance testing

Equipment used to collect images	The data set were acquired with P60/S60 series Digital Color Doppler Ultrasound System and probes in order to secure diversity of the data set: Mix of data from retrospective data collection and prospective data collection in clinical practice.
Reference standard	The ground truths drawn by five OB/GYN experts with more than 3 years' experience were cross-checked by the two experts with more than 20 years' experience and were re-checked by other four experts with more than 30 years' experience. Any images that do not meet the inclusion/exclusion criteria were excluded from the set of images.
Test Set	The test set used to test the standalone performance of S-Fetus^{AI} are independent of the training data set and tuning data set, which have been collected at three hospitals in China and meet the characteristics of independence, representativeness, uniformity of distribution, etc., and strive to include all possible scenarios in the clinic as far as possible. S-Fetus-Recognition: The number of test set is more than 200 images for each standard section; total 3717 images for 14 standard sections. S-Fetus-Measure:

	The number of test set is more than 250 for each standard section; total 2929 image for 9 standard sections.
Acceptance Criteria	The accuracy of the S-Fetus-Recognition is not less than 85%. The accuracy of the S-fetus-Measure is not less than 80%.
Test Results	The accuracy of the S-Fetus-Recognition is 90.01%. The accuracy of the S-fetus-Measure is 85%.

2) Clinical Performance testing

Research Device	P60 Exp Digital Color Doppler Ultrasound System with S-Fetus^{AI} & VC6-2 Probe
Research Group	**Trial group**: Automatic recognition and measurement of the S-Fetus^{AI} function of the Research Device; **Contrast group**: Manual recognition and measurement of the investigators (physicians with more than 3 years of specialized training in obstetric ultrasound examination; total 7 investigators). The section recognition results and precision of Sp of Trial group and Contrast group were evaluated by the 2 Readers from the independent evaluation group, which consists of three qualified professionals (senior experts who had been involved in prenatal ultrasound examination).
Sample Size	158 cases
Clinical Performance Evaluation & Acceptance Criteria	1.Identification Precision of the 14 Standard Sections (Primary Evaluation Indicator) Non-inferiority design is used. If the lower limit of the 95% CI for the difference of Identification Precision is greater than -10%, then the Identification Precision of the Standard Section of S-Fetus^{AI} function is considered non-inferior to manual recognition. 2. Measurement Error of Growth Parameters (Secondary Evaluation Indicator) 1) The relative errors of measurement for the 11 Growth Parameters; 2) The precision of Sp (spinal cord cone end positioning).
Conclusion	According to the clinical trial results, we can deduce that the recognition precision of the standard sections of S-Fetus^{AI} was not inferior to that of the manual scan, S-Fetus^{AI} has a good consistency with the manual measurement and the Sp (spinal cone end positioning) precision was basically equal between the trial group and control group.

6. Clinical Test Conclusion

The Subject device P60 Series Digital Color Doppler Ultrasound System did not require clinical studies

to demonstrate substantial equivalence.

7. Comparison with Predicate Devices

The Subject device P60 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 P60 Series Digital Color Doppler Ultrasound System has the same intended use and imaging modes as the predicate device P60 Series (K171000);
- The P60 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 P60 Series (K171000);
- The acoustic output levels of the P60 Series Digital Color Doppler Ultrasound System are below the limits of FDA, which are the same as the predicate device P60 Series (K171000);
- The P60 Series Digital Color Doppler Ultrasound System have supported six new probes, including L752, L2-9, L3-11, MC1-6, 3P-A and 2P1, which have been migrated from the predicate device S90 Exp Series (K222596) and P20 Elite Series (K221140);
- The P60 Series Digital Color Doppler Ultrasound System have supported five new biopsy brackets, including NGBL752, NGBL2-9, NGBMC1-6, NGB2P1 and NGB3P-A, which have been cleared with many ultrasound systems manufactured by SonoScape, including the predicate device P20 Elite Series (K221140) and S90 Exp Series (K222596).
- The P60 Series Digital Color Doppler Ultrasound System have the following new features (functions), including SR Flow, Micro F, S-Follicle, S-Endo, S-MSK,VCI, FreeVue, S-Live Contour, Color 3D, STIC, S-Spine, S-Pelvic Floor, 3D/4D HyCoSy, SPI, Sono-Synch, Sono-Drop and Sono Assistant, which have been migrated from the predicate device S90 Exp Series (K222596) and P20 Elite Series (K221140).
- The P60 Series Digital Color Doppler Ultrasound System add one new feature: S-Fetus^{AI}, which is carried out using the Artificial Intelligence or Machine Learning algorithm. The recognition precision of the standard sections of S-Fetus^{AI} is equivalent to that of the manual scan and the measurement precision of S-Fetus^{AI} is equivalent to the manual measurement and the Sp (spinal cone end positioning) precision is equivalent to that of the manual position.
- The P60 Series Digital Color Doppler Ultrasound System have the following new features (auto measurements), including Auto Bladder, Auto IMT, Auto EF, Auto NT, Auto OB, S-Endo. and S-Follicle, which have been migrated from the predicate device S90 Exp Series (K222596) and P20 Elite Series (K221140);
- The P60 Series Digital Color Doppler Ultrasound System add three new features (auto measurements), including S-Breast, S-Thyroid and S-hip, which are equivalent to the corresponding manual measurements cleared in the predicate device S90 Exp Series (K222596) and P20 Elite Series (K221140) and not based on AI/ML or deep learning-based technologies.

8. Conclusion

In accordance with 21 CFR Part 807 and based on the information provided, the subject device, P60 Series Digital Color Doppler Ultrasound System, and the predicate device have the same intended use. While there are differences in technological characteristics, these differences were evaluated with performance testing as described and the technological differences do not raise different questions of safety and effectiveness. Therefore, the results of the testing demonstrate that the subject device, P60 Series Digital Color Doppler Ultrasound System, is substantially equivalent to the predicate device.