September 15, 2022

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

Re: K221089
Trade/Device Name: P12 Elite Series Digital Color Doppler Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic Pulsed Doppler Imaging System
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: August 10, 2022
Received: August 15, 2022

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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 Kang, Ph.D.
Assistant Director
Mammography and Ultrasound Team
DHT 8C: 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221089

Device Name
P12 Elite Series Digital Color Doppler Ultrasound System

Indications for Use *(Describe)*
The P12 Elite Series Digital Color Doppler Ultrasound System (P12 Exp, P12 Elite, P12 Pro, R12, P12N, P11 Exp, P11 Elite, P11 Pro, R11, P11N, P10 Elite, P10N, R10, P9 Elite, M11,R9) is a general-purpose ultrasonic imaging instrument intended for use by a qualified and trained physician for ultrasound imaging, measurement, display and analysis of the human body and fluid, which is intended to be used in a hospital or medical clinic. The system is applicable for people who need clinical ultrasound examination. Age, weight, health condition and race are unlimited.
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), 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, Elastography, Contrast 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.

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510(k) Summary K221089

1. Submitter [21 CFR807.92 (a) (1)]

Submitter:	SONOSCAPE MEDICAL CORP.
Address:	Room 201 & 202, 12th Building, Shenzhen Software Park Phase II, 1 Keji Middle 2nd Road, Yuehai Subdistrict, Nanshan District, Shenzhen, 518057, Guangdong, China
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Email:	ra@sonoscape.net
Date Prepared	September 15, 2022

2. Device [21 CFR807.92 (a) (2)]

Trade Name:	P12 Elite Series Digital Color Doppler Ultrasound System
Models:	P12 Elite, P12 Exp, P12 Pro, R12, P12N, P11 Exp, P11 Elite, P11 Pro, R11, P11N, P10 Elite, P10N, R10, P9 Elite, M11, R9
Common Name:	Diagnostic Ultrasound System and Transducers

Classification Regulatory:

	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 Class:	II

3. Predicate Device(s) [21 CFR 807.92(a) (3)]

The identified predicate device within this submission is as follows:

Type	Manufacturer	Device	510 (K) Number
Primary Predicate Device	SONOSCAPE MEDICAL CORP.	P60 Series Digital Color Doppler Ultrasound System	K171000

Reference Devices	SONOSCAPE MEDICAL CORP.	S60 Elite Series/S70 Series Digital Color Doppler Ultrasound System	K201059

4. Device Description [21 CFR 807.92(a) (4)]

This SonoScape P12 Elite 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 and phased array.

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, Elastography, 3D/4D.

5. Intended Use [21 CFR 807.92(a) (5)]

The P12 Elite Series Digital Color Doppler Ultrasound System is a general-purpose ultrasonic imaging instrument intended for use by a qualified and trained physician for ultrasound imaging, measurement, display and analysis of the human body and fluid, which is intended to be used in a hospital or medical clinic. The system is applicable for people who need clinical ultrasound examination. Age, weight, health condition and race are unlimited.

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), 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, Elastography, Contrast and Combined modes: B/M, B/PWD, B/THI, M/Color M, B/Color Doppler, B/Color Doppler/PWD, B/Power Doppler/PWD.

6. Comparison with the Predicate device [21 CFR 807.92(a) (6)]

P12 Elite Series Digital Color Doppler Ultrasound System is comparable with and substantially equivalent to the predicate device:

Type	Manufacturer	Device	510 (K) Number
Primary Predicate Device	SONOSCAPE MEDICAL CORP.	P60 Series Digital Color Doppler Ultrasound System	K171000
Reference Devices	SONOSCAPE MEDICAL CORP.	S60 Elite Series/S70 Series Digital Color Doppler Ultrasound System	K201059

P12 Elite Series Digital Color Doppler Ultrasound System has almost the same intended uses, complies with the same regulation and safety standards, has the consistent acoustic output levels, has similar probes and technical characteristics with the predicate device legally marketed P60 Series (K171000).

Intended Use Comparison:

Compared with the predicate device P60 Series (K171000), the Subject Device P12 Elite Series has almost the same intended use. There are some additional information for subject device, including patient population and use environment, but all of them are also the same between the subject device and the primary predicate device.

Regulation and Safety Standards Comparison:

Compared with the predicate device P60 Series (K171000), the Subject Device P12 Elite Series comply with the same regulation and safety standards.

Acoustic Output Levels Comparison:

Compared with the predicate device P60 Series (K171000), the Subject Device P12 Elite Series have the consistent acoustic output levels.

Probes Comparison:

Compared with the predicate device P60 Series (K171000), the Subject Device P12 Elite Series have the similar probes. There are seven new probes, including C1-5, C361, 2P1, 3P-A, L741, L752 and 10L1; except the probe C1-5, all the others have been cleared with other Digital Color Doppler Ultrasound Systems manufactured by

SONOSCAPE MEDICAL CORP., such as P10 Series (K173058), P20 Series (K172993), S22 Series (K142815) and etc.

The new probe C1-5 has the same technical characteristics as the probe 3C-A, including probe type, central frequency, indications for use, operation mode, functions, material and manufacturing process. There is only small difference in size, which doesn't affect the safety, effectiveness and clinical use. There is no new risk raised in safety and effectiveness of the new probes. Therefore they can be considered Substantially Equivalent in safety and effectiveness, so the SE is not affected.

Biopsy bracket Comparison:

Compared with the predicate device P60 Series (K171000), the Subject Device P12 Elite Series have seven new biopsy brackets NGBC1-5, NGBC361, NGB2P1, NGB3P-A, NGBL741-2, NGBL752 and NGB10L1-2. Except the biopsy brackets NGBC1-5, NGBL741-2 and NGB10L1-2, all the others have been cleared in P10 Series and P20 Series Digital Color Doppler Ultrasound System (K173058, K172993), manufactured by SONOSCAPE MEDICAL CORP.

Compared with NGB3C-A, the new biopsy brackets NGBC1-5, NGBL741-2 and NGB10L1-2 have the same material, manufacturing process and reprocessing procedures, and have similar design and appearance; there is only small difference in the size between them, which doesn't affect reprocessing procedures. There is no new risk raised in safety and effectiveness of the new biopsy brackets. Therefore they can be considered Substantially Equivalent in safety and effectiveness, so the SE is not affected.

Technical Characteristics Comparison:

Compared with the predicate device P60 Series (K171000), the Subject Device P12 Elite Series have almost the same main technical features, including Design, Operation Controls, Operation Mode, Display Modes and Power Supply.

Compared with the predicate device P60 Series (K171000), the Subject Device P12 Elite Series have some newly added features in Function, including contrast imaging, S-Live/S-Live Silhouette, S-Depth, SR Flow, Auto Face, FreeVue and S-Fetus, which are the same as or similar with the imaging functions of the reference device S60 Elite Series/S70 Series Digital Color Doppler Ultrasound System (K201059); at the same time, the Subject Device P12 Elite Series have four accessibility functions, including S-MSK, Sono-help, Sono-Assistant and Sono-Synch, which is an assistant function or

used for teaching purpose.

Compared with the predicate device P60 Series (K171000), the Subject Device P12 Elite Series have some new features (Measurement Items), including AVC Follicle, Auto OB, Auto NT, Auto EF, Auto bladder, Auto IMT and S-Fetus, which are the same as or equivalent with the measurement functions of the reference device S60 Elite Series/S70 Series Digital Color Doppler Ultrasound System (K201059). The end user can edit, accept, or reject the measurements and can modify the measurement results at any point. The final output and its accuracy is controlled by the end user.

The differences in function and measurement items will not raise new risk and different questions of safety and effectiveness. Therefore they can be considered Substantially Equivalent in safety and effectiveness, the SE is not affected.

Summary of the comparison

Compared with the predicate device legally marketed SonoScape P60 Series (K171000) and S60 Elite Series/S70 Series Digital Color Doppler Ultrasound System (K201059), the subject device (P12 Elite Series Digital Color Doppler Ultrasound System) are all analyzed with the predicate device. The comparison showed that they can be considered Substantially Equivalent in safety and effectiveness. Therefore, there is no new risk raised, and the SE is not affected.

7. Non-Clinical Tests [21 CFR 807.92(b) (1)]

Non-clinical testing to assure compliance with electrical, mechanical, thermal and electromagnetic compatibility safety, acoustic output and biocompatibility were performed and have been found to conform to applicable standards. The P12 Elite Series has been designed and manufactured to meet the following standards:

IEC 60601-1:2005+A1:2012, Medical Electrical Equipment- Part 1: General requirements for basic safety and essential performance [08/20/2012];
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 [2014-02];
IEC 60601-2-37:2015 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 10993-5:2009, Biological Evaluation of Medical Devices, Part 5-Tests for in vitro cytotoxicity [06/01/2009];

ISO 10993-10:2010, Biological Evaluation of Medical Devices- Part 10: Tests for irritation and skin sensitization [08/01/2010];
AIUM/NEMA UD 2:2004 (R2009), Acoustic output measurement standard for diagnostic ultrasound equipment [08/21/2009].

The Digital Color Doppler Ultrasound System is verified through the relevant summarized information as followed:

Performance test	Testing protocols and fail/acceptance criteria	Testing results
Electrical safety testing	IEC 60601-1:2005+A1:2012	Passed
EMC testing	IEC 60601-1-2:2014	Passed
Acoustic testing	IEC 60601-2-37:2007+A1:2015 AIUM/NEMA UD 2:2004 (R2009)	Passed
Software Verification and Validation	IEC 62304:2006 +A1:2015	Passed

Laboratory tests (including Phantom tests) were conducted to verify that the P12 Elite Series met all design specifications and the P12 Elite Series conformed to applicable medical device standards.

8. Clinical Test [21 CFR 807.92(b) (2)]

No clinical testing was required.

9. Substantially Equivalent Conclusions [21 CFR 807.92(b) (3)]

In accordance with the 21 CFR Part 807 and based on the information provided in this premarket notification, SONOSCAPE MEDICAL CORP. concludes that P12 Elite Series Digital Color Doppler Ultrasound System is substantially equivalent to the predicate device with regard to safety and effectiveness.