



February 15, 2024

Medisono
% Jorge Millan
Biomedical Director
3016 NW 82nd Ave
MIAMI FL 33122

Re: K231659

Trade/Device Name: MS55 Plus Digital Color Doppler Ultrasound System (MS55); P25 Expert Digital Color Doppler Ultrasound System (P25 Expert); P12 Plus Digital Color Doppler Ultrasound System (P12 Plus); P11 Plus Portable Digital Color Doppler Ultrasound System (P11 Plus); P9 Plus Ultrasound Diagnostic System (P9 Plus); P3 Plus Ultrasound Diagnostic System (P3 Plus)

Regulation Number: 21 CFR 892.1550

Regulation Name: Ultrasonic pulsed doppler imaging system

Regulatory Class: Class II

Product Code: IYN, IYO, ITX

Dated: January 18, 2024

Received: January 19, 2024

Dear Jorge Millan:

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.

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

Submission Number (if known)

K231659

Device Name

MS55 Plus Digital Color Doppler Ultrasound System (MS55);
P25 Expert Digital Color Doppler Ultrasound System (P25 Expert);
P12 Plus Digital Color Doppler Ultrasound System (P12 Plus);
P11 Plus Portable Digital Color Doppler Ultrasound System (P11 Plus);
P9 Plus Ultrasound Diagnostic System (P9 Plus);
P3 Plus Ultrasound Diagnostic System (P3 Plus)

Indications for Use (Describe)

Indications for Use: The MEDISONO Ultrasonic Diagnostic Imaging System models P3 Plus, P9 Plus, P25 Expert, P12 Plus, P11 Plus, and MS55 plus are intended for diagnostic ultrasound imaging analysis of adults, pregnant women, pediatric patients in gynecology rooms, obstetrics rooms, examination rooms, intensive care units, and emergency rooms. The system is intended for use by or on the order of a physician or similarly qualified health care professional for ultrasound evaluation of Fetus, Abdomen, Pediatrics, Small Organ, Neonatal Cephalic, Cardiology, Peripheral Vessel, Musculo-skeleton (both Conventional and Superficial), Urology (including prostate), Transrectal and Transvaginal.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) Summary

Submitter Information

Submitter	Medisono 3016 NW 82 Ave Doral, FL-USA- 33122
Contact:	Jorge Millan, PhD
Telephone number	(786) 416-5587
E-mail	jmillan@sigmabiomedical.com
Date prepared:	February 15, 2024

Subject Device Name

Trade/Proprietary Name:	P3 Plus Ultrasound Diagnostic System (P3 Plus), P9 Plus Ultrasound Diagnostic System (P9 Plus), P11 Plus Portable Digital Color Doppler Ultrasound system (P11 Plus), P12 Plus Digital Color Doppler Ultrasound System (P12 Plus), P25 Expert Digital Color Ultrasound system (P25 Expert), MS55 Plus Digital Color Doppler Ultrasound system (MS55 Plus)
Regulation Number:	892.1550
Regulation Name:	Ultrasonic pulsed doppler imaging system
Product Code:	IYN, IYO, ITX
Class	II
Panel	Radiology

Primary Predicate Device

Predicate Device:	Sonoscape P60 Ultrasound System
Sponsor	Sonoscape
510(K)	K171000
Regulation Number:	892.1550
Regulation Name:	Ultrasonic pulsed doppler imaging system
Product Code:	IYN, IYO, ITX
Class	II
Panel	Radiology

K231659 MEDISONO 510K Summary – Feb 15, 2024

Reference Device:	ECO 5, ECO 2
Sponsor	Chison
510(K)	K131305
Regulation Number:	892.1550
Regulation Name:	Ultrasonic pulsed doppler imaging system
Product Code:	IYN, IYO, ITX
Class	II
Panel	Radiology

Reference Device:	P20, P15
Sponsor	Sonoscape
510(K)	K172993
Regulation Number:	892.1550
Regulation Name:	Ultrasonic pulsed doppler imaging system
Product Code:	IYN, IYO, ITX
Class	II
Panel	Radiology

Reference Device:	S8 Portable Digital Color Doppler Ultrasound System
Sponsor	Sonoscape
510(K)	K132768
Regulation Number:	892.1550
Regulation Name:	Ultrasonic pulsed doppler imaging system
Product Code:	IYN, IYO, ITX
Class	II
Panel	Radiology

Device Description:

The P3 Plus Ultrasound Diagnostic System is a portable digital B/W compact ultrasound system with diagnostic B/W image quality and PW Doppler capability, applied in ultrasound diagnostic examination of abdominal, Vascular, Small Parts, Musculoskeletal, Obstetrics and Gynecology applications. It is designed to produce ultrasound waves into body tissue and to present the returned echo information on the monitor. The resulting information is displayed in six display modes: B-Mode, B+B, 4B Mode, M-Mode, B+M Mode, and PW. This system controlled by software employs an array of probes that include linear array, convex linear array, microconvex linear array, transrectal and transvaginal with a frequency range of approximately 2.5MHz- 11MHz. The system consists of a main unit, transducers, and other accessories.

The P9 Plus Ultrasound Diagnostic System is a portable digital compact ultrasound system with multiple imaging modes applied in ultrasound diagnostic examination of f Fetal/OB; Abdominal (GYN & Urology); Pediatric; Small Organ (breast, testicle, thyroid); Cardiac (adult & pediatric); Peripheral Vascular; Musculo-skeletal Conventional & Superficial; Transrectal and Transvaginal applications. It is designed to produce ultrasound waves into body tissue and to present the returned echo information on the monitor, with multiple imaging modes: B-mode, C-mode, M-mode, CW-mode, PW-mode, and PDI mode that employs an array of probes that include linear, Convex and Phase Array probes with a frequency range of approximately 2MHz- 11MHz. The system consists of a main unit, transducers, and other accessories.

The P11 Plus Portable Digital Color Doppler Ultrasound System is a portable ultrasound system with Cardiac measurements, 4D, Elastography and Stress Echo capabilities. It is designed to produce ultrasound waves into body tissue and to present the returned echo information on the monitor; with complete imaging modes: 2D with THI, Color M, CFM, PDI, PW, HPRF, CW. This system contains an array of probes that include full range of Linear, Convex, Phased Array, Endocavity, TEE, Volumetric, and Biplane TRT probes with high density broadband transducers with Frequency up to 16 MHz. The system consists of a main unit, a display and transducers.

The MS55 Plus Digital Color Doppler Ultrasound System is a diagnostic ultrasound system, which applies advanced ultrasonic Doppler technologies such as Harmonic Compound Imaging, Panoramic Imaging, and Spatial Compounding Imaging, with capabilities for applications in of Fetal, Abdominal, Pediatric, Small Organ (breast, testes, thyroid), Cephalic (neonatal and adult), Transrectal, Trans-vaginal, Peripheral Vascular, Cerebral Vascular, Musculoskeletal (Conventional and Superficial), Cardiac (pediatric and adult), Trans-esoph (Cardiac), Laparoscopic, OB/ Gyn and Urology. Various image parameter adjustments, 22-inch LED, 13.3-inch touchscreen and diverse probes are configured to provide clear and stable images. Its function is to acquire and display Ultrasound images in Micro F mode, CFM mode, PW mode, SR-Flow mode, PDI/DPDI mode, TDI mode. This system provides a series of probes that include phased array, convex array, curved array, and abdominal volume probe.

The P12 Plus Digital Color Doppler Ultrasound System is a diagnostic imaging system, which applies device advanced ultrasonic Doppler technologies such as Harmonic Compound Imaging, Panoramic Imaging, and Spatial Compounding Imaging, with capabilities for applications in Fetal, Abdominal, Pediatric, Small Organ (breast, testes, thyroid), Cephalic (neonatal and adult), Transrectal, Trans-vaginal, Peripheral Vascular, Cerebral Vascular, Musculo-skeletal (Conventional and Superficial), Cardiac (pediatric and adult), Trans-esoph.(Cardiac), Laparoscopic, OB/Gyn and Urology. Various image parameter adjustments, 22-inch LED, 13.3-inch touch screen and diverse probes are configured to provide clear and stable images. Its function is to acquire and display Ultrasound images in Micro F mode, CFM mode, PW mode, SR-Flow mode, PDI/DPDI mode, TDI mode. This system provides a series of probes that include Linear, Convex, Phased Array, Endocavity, TEE, Intraoperative, Volumetric, and Biplane TRT probes, wide scanning Angle Endo-Cavity Probe with frequency ranges of 1.9 MHz to 17MHZ.

The P25 Expert Digital Color Doppler Ultrasound System is a diagnostic imaging system, which applies advanced ultrasonic Doppler technologies such as Harmonic Compound Imaging, Panoramic Imaging, and Spatial Compounding Imaging, with capabilities for applications in Fetal, Abdominal, Pediatric, Small Organ (breast, testes, thyroid), Cephalic (neonatal and adult), Transrectal, Trans-vaginal, Peripheral Vascular, Cerebral Vascular, Musculo-skeletal (Conventional and Superficial), Cardiac (pediatric and adult), Trans-esoph.(Cardiac), Laparoscopic, OB/Gyn and Urology. Various image parameter adjustments, 22-inch LED, 13.3-inch touch screen and diverse probes are configured to provide clear and stable images. Its function is to acquire and display Ultrasound images in 2D with THI, Color M, CFM, PDI, PW, HPRF, CW, Contrast Imaging, Elastography, Stress Echo. This system provides a series of probes that include Linear, Convex, Phased Array, Endocavity, TEE, Intraoperative, Volumetric, and Biplane TRT probes, wide scanning Angle Endo-Cavity Probe probes, wide scanning Angle Endocavity Probe with frequency ranges of 1.9 MHz to 17MHZ.

Indications for Use:

The MEDISONO Ultrasonic Diagnostic Imaging System models P3 Plus, P9 Plus, P25 Expert, P12 Plus, P11 Plus, and MS55 Plus are intended for diagnostic ultrasound imaging analysis of adults, pregnant women, pediatric patients in gynecology rooms, obstetrics rooms, examination rooms, intensive care units, and emergency rooms. The system is intended for use by or on the order of a physician or similarly qualified health care professional for ultrasound evaluation of Fetus, Abdomen, Pediatrics, Small Organ, Neonatal Cephalic, Cardiology, Peripheral Vessel, Musculo-skeleton (both Conventional and Superficial), Urology (including prostate), Transrectal and Transvaginal.

Non-Clinical Data:

Non-clinical product evaluation to demonstrate safety and effectiveness was conducted. Non-clinical testing includes:

Software Verification and Validation

Software verification and validation testing were conducted on the Medisono MS55, P25 Expert, P12 Plus, P11 Plus, P9 Plus, P3 Plus and documentation is provided as recommended by FDA's Guidance for the Content of Premarket Submissions for Software Contained Medical Devices. The software for the devices is considered as moderate level of concern, since a failure or latent flaw in the software would lead to a delayed delivery of appropriate medical care. Documentation includes level of concern, software requirements and specifications, design architecture, risk analysis and software validation and verification.

Performance Testing (Measurement Accuracy) was conducted on the Medisono MS55, P25 Expert, P12 Plus, P11 Plus, P9 Plus, P3 Plus to determine measurement accuracy when performing the various distance and area measurements. Acoustic testing, EMC, and doppler sensitivity measurements were also performed. Safety testing includes acoustic output testing as per the IEC 60601-2-37 standard, IEC 60601-1 and IEC 60601-1-2 standards.

Predicate Devices

Comparison with the Predicate Devices [21 CFR 807.92(a) (6)]:

The proposed system models are substantially equivalent to diagnostic ultrasound systems cleared for marketing in the US. The MEDISONO model P3 Plus is equivalent to the ECO 2 ultrasound system (K131305) made by Chison; the P9 Plus model is equivalent to the ECO 5 ultrasound system (K131305) made by Chison, the P25 Expert model is equivalent to the P20 Digital Color Doppler Ultrasound System (K172993) made by Sonoscape, the P12 Plus model is equivalent to the P15 made by Sonoscape (K172993), the P11 Plus is equivalent to the S8 Portable Digital Color Doppler Ultrasound system (K132768) made by Sonoscape, and the MS55 Plus ultrasound system is equivalent to the P60 Ultrasound system made by Sonoscape (K171000). The subject and predicate devices incorporate identical software packages, imaging functions, and display functions. The designs of the subject and predicate devices are also the same.

Technical Characteristics Comparison:

The basic and main technical features of the subject device are the same as the predicate device.

Feature Comparison:

Subject device has similar features and functionality as the predicate device:

Product Comparison

Common Name	Subject Device MS55 Diagnostic Imaging System	Predicate Device P60 Diagnostic Ultrasound System
Owner	Medisono (K231659)	Sonoscape (K171000)
Indications for use	The MEDISONO Ultrasonic Diagnostic Imaging System models P3 Plus, P9 Plus, P25 Expert, P12 Plus, P11 Plus, and MS55 plus are intended for diagnostic ultrasound imaging analysis of adults, pregnant women, pediatric patients in gynecology rooms, obstetrics rooms, examination rooms, intensive care units, and emergency rooms. The system is intended for use by or on the order of a physician or similarly qualified health care professional for ultrasound evaluation of Fetus, Abdomen, Pediatrics, Small Organ, Neonatal Cephalic, Cardiology, Peripheral Vessel, Musculo-skeleton (both Conventional and Superficial), Urology (including prostate), Transrectal and Transvaginal.	The Digital Color Doppler Ultrasound System is a general-purpose ultrasonic imaging instrument intended for use by a qualified physician for evaluation of 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-esophageal (Cardiac), Laparoscopic, OB/Gyn and Urology.
Display modes	B mode, M Mode, quad mode, TDI, PDI, PW, CW mode	B mode, M Mode, quad mode, TDI, PDI, PW, CW mode
Image Gray Scale	256	256
Storage	500GB HDD	500GB HDD
Cine Review	Standard cine memory up to 2729 frames	Standard cine memory up to 2729 frames
Depth Adjustment	Fully adjustable depth adjustment	Fully adjustable depth adjustment
Image Conversion	Up/Down flip, Left/Right flip, 90° rotate, B/W invert	Up/Down flip, Left/Right flip, 90° rotate, B/W invert
Auto Image Analysis	Fetus, Thyroid, Pelvic Floor, Endo, Follicle, Spine, MSK	Fetus, Thyroid, Pelvic Floor, Endo, Follicle, Spine, MSK

K231659 MEDISONO 510K Summary – Feb 15, 2024

B mode Measurement	Distance, two-point, distance ratio, two-line, length trace, %stenosis difference, polyline, area, trace area, point area, ellipse area, area ratio, %stenosis area, volume, three distance, ellipse+ distance, angle (three-point, two line).	Distance, two-point, distance ratio, two-line, length trace, %stenosis difference, polyline, area, trace area, point area, ellipse area, area ratio, %stenosis area, volume, three distance, ellipse+ distance, angle (three-point, two line).
M mode Measurement	Distance, slope, %stenosis distance, distance ratio, time, heart rate,	Distance, slope, %stenosis distance, distance ratio, time, heart rate,
Doppler Measurement	Velocity, acceleration, resistivity index measurement, pulsatility index measurement, S/D ratio, auto trace, semi auto trace, manual trace, time, heart rate.	Velocity, acceleration, resistivity index measurement, pulsatility index measurement, S/D ratio, auto trace, semi auto trace, manual trace, time, heart rate.
Annotations	Patient ID, patient name, date of birth, sex, description, requested procedure ID, accession #, date/time.	Patient ID, patient name, date of birth, sex, description, requested procedure ID, accession #, date/time.
Body Mark	130 types	130 types
USB Port	USB 2.0	USB 2.0
Display	LCD 22 inch	LCD 22 inch
Operating Voltage	100V-240V	100V to 120 V, 200V to 240V
Operating Frequency	50/60 Hz	50/60Hz
Input current	3.5 amps-7.5 amps	3.5 amps-7.5 amps
Capacity	9.6Ah/142.08Wh/138.24Wh	9.6Ah/142.08Wh/138.24Wh
Voltage	14.8V/14.4V	14.8V/14.4V
Average Working time	>1hr	>1hr
Maximum charging time	8 hr.	8 hr.
Ambient Temperature for Operation	10°C ~ 40°C	10°C to +40°C
Relative Humidity for operation	30% ~ 75% (no condensation)	30% ~ 75% (no condensation)
Temperature for Transport and Storage	-20°C ~ +55°C	-20°C ~ +55°C
Relative humidity range for Transport and Storage	20% ~ 90% (no condensation)	20% ~ 90% (no condensation)

Item	Candidate Device	Predicate Device
Common Name	P25 Expert Digital Color Doppler Ultrasound System	Ultrasonic Diagnostic Ultrasound system Model P20
Owner	Medisono K231659	Sonoscape (K172993)

Indications for use	The MEDISONO Ultrasonic Diagnostic Imaging System models P3 Plus, P9 Plus, P25 Expert, P12 Plus, P11 Plus, and MS55 plus are intended for diagnostic ultrasound imaging analysis of adults, pregnant women, pediatric patients in gynecology rooms, obstetrics rooms, examination rooms, intensive care units, and emergency rooms. The system is intended for use by or on the order of a physician or similarly qualified health care professional for ultrasound evaluation of Fetus, Abdomen, Pediatrics, Small Organ, Neonatal Cephalic, Cardiology, Peripheral Vessel, Musculo-skeleton (both Conventional and Superficial), Urology (including prostate), Transrectal and Transvaginal.	The Digital Color Doppler Ultrasound System is a general-purpose ultrasonic imaging instrument intended for use by a qualified physician for evaluation of 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), Transesophageal (Cardiac), Laparoscopic, OB/Gyn and Urology.
Display modes	B mode, M Mode, quad mode, TDI, PDI, PW, CW mode	B mode, M Mode, quad mode, TDI, PDI, PW, CW mode
Image Gray Scale	256	256
Storage	500 GB HDD	500 GB HDD
Cine Review	498 frames	498 frames
Depth Adjustment	Adjustable in real time in all modes.	Adjustable in real time in all modes.
Image Conversion	Up/Down flip, Left/Right flip, 90°rotate, B/W invert, zoom	Up/Down flip, Left/Right flip, 90°rotate, B/W invert, zoom

K231659 MEDISONO 510K Summary – Feb 15, 2024

Software Packages	Cardio-vascular Premium PLUS Kit: TDI / Color M / ECG / Steer M / Color 3D OB / GYN Premium PLUS Kit: Multi Slice View / Oblique View / 3D Rendering (S-Live, S-Depth) / MagiCut / SmartCut / 3D μ scan / Auto Face / 3D Measurement / Pelvic Floor Ultrasound, Abdomen Package Gynecology Package Obstetrics Package Cardiology Package Small parts Package Urology Package Vascular Package Pediatrics Package	Cardio-vascular Premium PLUS Kit: TDI / Color M / ECG / Steer M / Color 3D OB / GYN Premium PLUS Kit: Multi Slice View / Oblique View / 3D Rendering (S-Live, S-Depth) / MagiCut / SmartCut / 3D μ scan / Auto Face / 3D Measurement / Pelvic Floor Ultrasound, Abdomen Package Gynecology Package Obstetrics Package Cardiology Package Small parts Package Urology Package Vascular Package Pediatrics Package
B mode Measurement	Distance, two-point, length trace, two-line, distance ratio, %stenosis distance, area, trace area, point area, ellipse area, area ratio, %stenosis area, volume, angle,	Distance, two-point, length trace, two-line, distance ratio, %stenosis distance, area, trace area, point area, ellipse area, area ratio, %stenosis area, volume, angle,
M mode Measurement	Distance, slope, %stenosis distance, distance ratio, time, heart rate,	Distance, slope, %stenosis distance, distance ratio, time, heart rate,
Doppler Measurement	Velocity, acceleration, resistivity index, pulsatility index, S/D ratio, auto trace, manual trace, time, heart rate.	Velocity, acceleration, resistivity index, pulsatility index, S/D ratio, auto trace, manual trace, time, heart rate.
Color Flow-Mode Measurement	Doppler area, color flow, flow velocity,	Doppler area, color flow, flow velocity,
Annotations	Patient name, age, sex, time, date, hospital name, doctor name, comment (full screen character editing)	Patient name, age, sex, time, date, hospital name, doctor name, comment (full screen character editing)
Body Mark	130	130
USB Port	USB 2.0	USB 2.0
Display	21.5" High Resolution LED Color Monitor	21.5" High Resolution LED Color Monitor
Diagonal Size	21.5 inch	21.5 inch
Operating Voltage	100-127V/220-240V	100-127V/220-240V
Operating Frequency	50/60Hz	50/60Hz

K231659 MEDISONO 510K Summary – Feb 15, 2024

Capacity	9.6 Ah/142Wh	9.6 Ah/142Wh
Voltage	14.8 V	14.8 V
Average Working time	>1hr	>1hr
Main unit dimension	751×518×1350mm	751×518×1350mm
Net weight	86 kg	86 kg

Item	Candidate Device	Predicate Device
Common Name	P12 Plus Digital Color Doppler Ultrasound System	Ultrasonic Diagnostic Ultrasound System Model P15
Owner	Medisono K231659	Sonoscape (K172993)
Indications for use	The MEDISONO Ultrasonic Diagnostic Imaging System models P3 Plus, P9 Plus, P25 Expert, P12 Plus, P11 Plus, and MS55 plus are intended for diagnostic ultrasound imaging analysis of adults, pregnant women, pediatric patients in gynecology rooms, obstetrics rooms, examination rooms, intensive care units, and emergency rooms. The system is intended for use by or on the order of a physician or similarly qualified health care professional for ultrasound evaluation of Fetus, Abdomen, Pediatrics, Small Organ, Neonatal Cephalic, Cardiology, Peripheral Vessel, Musculo-skeleton (both Conventional and Superficial), Urology (including prostate), Transrectal and Transvaginal.	The Digital Color Doppler Ultrasound System is a general-purpose ultrasonic imaging instrument intended for use by a qualified physician for evaluation of 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), Transesophageal (Cardiac), Laparoscopic, OB/Gyn and Urology.
Display modes	B mode, M Mode, quad mode, TDI, PDI, PW, CW mode	B mode, M Mode, quad mode, TDI, PDI, PW, CW mode
Image Gray Scale	256	256

K231659 MEDISONO 510K Summary – Feb 15, 2024

Item Common Name Owner	Candidate Device P12 Plus Digital Color Doppler Ultrasound System Medisono (K231659)	Predicate Device Model P15 Ultrasonic Diagnostic Ultrasound System Sonoscape (K172993)
Storage	500 GB HDD	500GB HDD
Cine Review	498 frames	498 frames
Software Packages	μ-scan speckle reduction, compound imaging, TDI, stress echo, C-Xlasto elastography and contrast imaging, Cardio-vascular Premium PLUS Kit: TDI / Color M / ECG / Steer M / Color 3D, OB / GYN Premium PLUS Kit: Multi Slice View / Oblique View / 3D Rendering (SLive, S-Depth) / MagiCut / SmartCut / 3D μscan / Auto Face / 3D Measurement / Pelvic Floor Ultrasound	μ-scan speckle reduction, compound imaging, TDI, stress echo, C-Xlasto elastography and contrast imaging, Cardio-vascular Premium PLUS Kit: TDI / Color M / ECG / Steer M / Color 3D, OB / GYN Premium PLUS Kit: Multi Slice View / Oblique View / 3D Rendering (SLive, S-Depth) / MagiCut / SmartCut / 3D μscan / Auto Face / 3D Measurement / Pelvic Floor Ultrasound
B mode Measurement	Distance, Area, Volume, angle.	Distance, Area, Volume, angle.
M mode Measurement	Distance, slope, %stenosis, distance ratio, time, heart rate.	Distance, slope, %stenosis, distance ratio, time, heart rate.
Color Flow-Mode Measurement	Doppler area, color flow, flow velocity.	Doppler area, color flow, flow velocity.
Doppler Measurement	Velocity, acceleration, resistivity index, pulsatility index, S/D ratio, auto trace, manual trace, time, heart rate.	Velocity, acceleration, resistivity index, pulsatility index, S/D ratio, auto trace, manual trace, time, heart rate.
Annotations	Patient name, age, sex, time, date, hospital name, doctor name, comment (full-screen character editing)	Patient name, age, sex, time, date, hospital name, doctor name, comment (full-screen character editing)
Body Mark	130 types	130 types
USB Port	USB 2.0, USB 3.0	USB 2.0, USB 3.0
Display	HD LED	HD LED
Diagonal Size	21.5 inch	21.5 inch
Pixel Number	1,920x1,080	1,920x1,080
Operating Voltage	100-127V/220-240V	100-127V/220-240V
Operating Frequency	50/60Hz	50/60Hz
Capacity	6.2Ah/89.28Wh	6.2Ah/89.28Wh

K231659 MEDISONO 510K Summary – Feb 15, 2024

Voltage	14.4 V	14.4 V
Average Working time	90 minutes	90 minutes
Main unit dimension	-With a 18.5 inch monitor, approx. 518mm(W)×1335mm(H)×751mm(D) (The height is measured when the monitor and control panel are in their lowest positions.) – With a 21.5 inch monitor, approx. 526mm(W)×1360mm(H)×751mm(D) (The height is measured when the monitor and control panel are in their lowest positions.)	-With a 18.5 inch monitor, approx. 518mm(W)×1335mm(H)×751mm(D) (The height is measured when the monitor and control panel are in their lowest positions.) – With a 21.5 inch monitor, approx. 526mm(W)×1360mm(H)×751mm(D) (The height is measured when the monitor and control panel are in their lowest positions.)
Net weight	86 kg	86 kg

Item	Candidate Device	Predicate Device
Common Name	P11 Plus Portable Digital Color Doppler Ultrasound System	Ultrasonic Diagnostic Ultrasound System Model S8
Owner	Medisono (K231659)	Sonoscape (K132768)
Indications for use	The MEDISONO Ultrasonic Diagnostic Imaging System models P3 Plus, P9 Plus, P25 Expert, P12 Plus, P11 Plus, and MS55 plus are intended for diagnostic ultrasound imaging analysis of adults, pregnant women, pediatric patients in gynecology rooms, obstetrics rooms, examination rooms, intensive care units, and emergency rooms. The system is intended for use by or on the order of a physician or similarly qualified health care professional for ultrasound evaluation of Fetus, Abdomen, Pediatrics, Small Organ, Neonatal Cephalic, Cardiology, Peripheral Vessel, Musculo-skeleton (both Conventional and Superficial), Urology	The Sonoscape S8 Exp device is a general purpose ultrasonic imaging instrument intended for use by a qualified physician for evaluation of Fetal, Abdominal, Pediatric, Small Organ (breast, testes, thyroid), Cephalic (neonatal and adult), Peripheral Vascular, Musculo-skeletal (Conventional and Superficial), Cardiac (neonatal and adult), OB/Gyn and Urology.

K231659 MEDISONO 510K Summary – Feb 15, 2024

	(including prostate), Transrectal and Transvaginal.	
Display modes	Triplex, B mode, M mode, TDI, CW, PW, CFM mode, PDI mode.	Triplex, B mode, M mode, TDI, CW, PW, CFM mode, PDI mode.
Image Gray Scale	256 levels	256 levels
Storage	500 GB HDD, optional 1TB	500 GB HDD, optional 1TB
Cine Review	498 frames	498 frames
Depth Adjustment	Adjustable in real time in all modes.	Adjustable in real time in all modes.
Image Conversion	Up/Down flip, Left/Right flip, 90°rotate, B/W invert	Up/Down flip, Left/Right flip, 90°rotate, B/W invert
Software Packages	Stress echo, TDI, Steer M, IMT, and Automatic flow volume analysis,	Stress echo, TDI, Steer M, IMT, and Automatic flow volume analysis,
B mode Measurement	Distance, two-point, length trace, two-line, distance ratio, %stenosis distance, area, trace area, point area, ellipse area, area ratio, %stenosis area, volume, ellipse+distance, angle, three-point angle, two-line angle.	Distance, two-point, length trace, two-line, distance ratio, %stenosis distance, area, trace area, point area, ellipse area, area ratio, %stenosis area, volume, ellipse+distance, angle, three-point angle, two-line angle.
M mode Measurement	Distance, slope, %stenosis, distance ratio, time, heart rate.	Distance, slope, %stenosis, distance ratio, time, heart rate.
Doppler Measurement	velocity, acceleration, resistivity index, pulsatility index, S/D ratio, auto/manual trace, time, heart rate.	velocity, acceleration, resistivity index, pulsatility index, S/D ratio, auto/manual trace, time, heart rate.
Annotations	Patient name, age, sex, time, date, hospital name, doctor name, comment (full screen character editing)	Patient name, age, sex, time, date, hospital name, doctor name, comment (full screen character editing)
Body Mark	130	130
USB Port	USB 2.0	USB 2.0
Display	LCD anti-glare	LCD anti-glare
Diagonal Size	15 inch	15 inch
Operating Voltage	110V-240V	110V-240V
Operating Frequency	50Hz/60Hz	50Hz/60Hz
Capacity	9.6Ah/142Wh	9.6Ah/142Wh
Voltage	14.8V	14.8V
Average Working time	>1 hour	>1 hour

K231659 MEDISONO 510K Summary – Feb 15, 2024

Ambient Temperature for Operation	10°C~+40°C	10°C~+40°C
Relative Humidity for operation	30%~75% (no condensation)	30%~75% (no condensation)
Atmospheric pressure range for operation	700hPa~1060hPa	700hPa~1060hPa
Temperature for Transport and Storage	-20°C~+55°C	-20°C~+55°C
Relative humidity range for Transport and Storage	20%~90% (no condensation)	20%~90% (no condensation)
Atmospheric temperature range for storage	700hPa~1060hPa	700hPa~1060hPa

Item	Candidate Device	Predicate Device
Common Name	P9 Plus Ultrasound Diagnostic System	Ultrasonic Diagnostic Imaging System Model ECO 5
Owner	Medisono (K231659)	Chison (K131305)
Indications for use	The MEDISONO Ultrasonic Diagnostic Imaging System models P3 Plus, P9 Plus, P25 Expert, P12 Plus, P11 Plus, and MS55 plus are intended for diagnostic ultrasound imaging analysis of adults, pregnant women, pediatric patients in gynecology rooms, obstetrics rooms, examination rooms, intensive care units, and emergency rooms. The system is intended for use by or on the order of a physician or similarly qualified health care professional for ultrasound evaluation of Fetus, Abdomen, Pediatrics, Small Organ, Neonatal Cephalic, Cardiology, Peripheral Vessel, Musculo-skeleton (both Conventional and Superficial), Urology (including prostate), Transrectal and Transvaginal.	The device is a general-purpose ultrasonic imaging instrument intended for use by a qualified physician for evaluation of Fetal/OB, Abdominal (GYN & Urology); Pediatric; Small Organ (breast, testes, thyroid); Cardiac (adult & pediatric); Peripheral Vascular, Musculo-skeletal Conventional & Superficial, Transrectal and Transvaginal

K231659 MEDISONO 510K Summary – Feb 15, 2024

Display modes	B Mode: Single, Dual, Quad C Mode: B/C(Single, Dual); Simultaneous dual mode: B+B/C; Triplex mode B/C/PW PDI/DPDI Mode: B/PDI(DPDI)(Single, Dual); Simultaneous dual mode: B+B/PDI(DPDI); Triplex mode B/PDI(DPDI)/PW Mode: B/PW (duplex, simultaneous); B+C/PW, B+PDI(DPDI)/PW (duplex); B/C/PW, B/PDI(DPDI)/PW (triplex); M Mode: B/M (Display layout: Up/down, Left/right,1:1)	B Mode: Single, Dual, Quad C Mode: B/C(Single, Dual); Simultaneous dual mode: B+B/C; Triplex mode B/C/PW PDI/DPDI Mode: B/PDI(DPDI)(Single, Dual); Simultaneous dual mode: B+B/PDI(DPDI); Triplex mode B/PDI(DPDI)/PW Mode: B/PW (duplex, simultaneous); B+C/PW, B+PDI(DPDI)/PW (duplex); B/C/PW, B/PDI(DPDI)/PW (triplex); M Mode: B/M (Display layout: Up/down, Left/right,1:1)
Image Gray Scale	256 levels	256 levels
Image magnification	In area Real time: ×1.2, ×1.4, ×1.6, ×2.0, ×2.4, ×3.0, ×4.0 Frozen: ×1.14, ×1.33, ×1.6, ×2.0, ×2.67, ×3.2, ×4.0	In area Real time:×1.2, ×1.4, ×1.6, ×2.0, ×2.4, ×3.0, ×4.0 ; Frozen: ×1.14, ×1.33, ×1.6, ×2.0, ×2.67, ×3.2, ×4.0
Storage	16 GB SSD	504 MB
Cine Review	409 frames (Color) / 1227frames (Black & White)	409 frames (Color)/. 1227frames (Black & White)
Depth Adjustment	Adjustable in real time in all modes	Adjustable in real time in all modes
Image Conversion	Up/Down flip, Left/Right flip, 90° rotate, B/W invert	Up/Down flip, Left/Right flip, 90°rotate, B/W invert
Software Packages	Abdomen, obstetric, small parts, gynecology, cardiology, urology, vascular.	Abdomen, obstetric, small parts, gynecology, cardiology, urology, vascular and Pediatrics.
B mode Measurement	Distance, circumference, area, volume, ratio, % stenosis, angle, and histogram.	Distance, circumference, area, volume, ratio, % stenosis, angle, and histogram.
M mode Measurement	Distance, time, slope, and heart rate	Distance, time, slope, and heart rate
Doppler Measurement	Time, heart rate, velocity, acceleration, RI, PI and Auto (auto trace)	Time, heart rate, velocity, acceleration, RI, PI and Auto (auto trace)
Annotations	Patient name, age, sex, time, date, hospital name, doctor name, comment (full screen character editing)	Patient name, age, sex, time, date, hospital name, doctor name, comment (full-screen character editing)
Body Mark	130 types	130 types

K231659 MEDISONO 510K Summary – Feb 15, 2024

USB Port	USB 2.0	USB 1.1
Operating Voltage	100V-250V	100V-240V
Operating Frequency	50 Hz/60 Hz	50 Hz/60 Hz
Input current	1.8A-0.8A	1.8A-0.8A
Capacity	6400 mAh	6400 mAh
Voltage	14.8 VDC	14.8 VDC
Average Working time	1.5 h	1.5 h
Maximum charging time	8 h	8 h
Cycle Life	300 times	300 times
Ambient Temperature for Operation	10 °C~40 °C	+5 °C ~ +40 °C
Relative Humidity for operation	30%~75%RH	25% RH ~ 80% RH (noncondensing)
Atmospheric pressure range for operation	700hPa~1060hPa	860 hPa ~ 1060 hPa
Temperature for Transport and Storage	-5° C ~ 40° C	-20 °C ~ +55 °C
Relative humidity range for Transport and Storage	≤ 80% non-condensing	25% RH ~ 93% RH (noncondensing)
Atmospheric pressure range for Transport and Storage	700hPa ~ 1060hPa	700 hPa ~ 1060 hPa

Item Common Name	Candidate Device P3 Plus Ultrasound Diagnostic System	Predicate Device Ultrasonic Diagnostic System ECO 2
Owner	Medisono (K231659)	Chison (K131305)
	The MEDISONO Ultrasonic Diagnostic Imaging System models P3 Plus, P9 Plus, P25 Expert, P12 Plus, P11 Plus, and MS55 plus are intended for diagnostic ultrasound imaging analysis of adults, pregnant women, pediatric patients in gynecology rooms, obstetrics rooms, examination rooms, intensive care units, and emergency rooms. The system is intended for use by or on the order of a physician or similarly qualified health care professional for ultrasound	The device is a general-purpose ultrasonic imaging instrument intended for use by a qualified physician for evaluation of Fetal/OB, Abdominal (GYN & Urology); Pediatric; Small Organ (breast, testes, thyroid); Cardiac (adult & pediatric); Peripheral Vascular, Musculo-skeletal Conventional & Superficial, Transrectal and Transvaginal

K231659 MEDISONO 510K Summary – Feb 15, 2024

	evaluation of Fetus, Abdomen, Pediatrics, Small Organ, Neonatal Cephalic, Cardiology, Peripheral Vessel, Musculo-skeleton (both Conventional and Superficial), Urology (including prostate), Transrectal and Transvaginal.	
Display modes	B-Mode, B+B, 2B, 4B Mode, M Mode, B+M Mode, and PW	B, 2B, 4B, B+M, M, and PW Mode
Image Gray Scale	256 levels	256 levels
Image magnification	x1 .0. x1 .2, x1 .4, x1 .6, x2.0, x2.4, x3.0, x4.0 in distance	In area Real time: 100%, 144%,196%, 256%, 400%, 576%, 900%, 1600% Frozen (only available in B mode): 100%, 178%, 400%,1600
Storage	504 MB	504 MB
Cine Review	256 frames	256 frames
Depth Adjustment	Adjustable in real time in B, 2B, 4B, B+M, M, and PW modes	Adjustable in real time in B, 2B, 4B, B+M, M, and PW modes
Frame Correlation Coefficient	8 levels to adjust (0~7), (B, 2B, 4B, B+M modes, ineffective when freezing)	8 levels to adjust (0~7), (B, 2B, 4B, B+M modes, ineffective when freezing)
Image Conversion	Up/Down flip, Left/Right flip, 90°rotate	Up/Down flip, Left/Right flip, 90°rotate
Software Packages	Obstetric, small parts, gynecology, orthopedics, cardiology, urology, or vascular	Obstetric, small parts, gynecology, orthopedics, cardiology, urology, or vascular
B mode Measurement	Distance, circumference, area, volume, ratio, % stenosis, histogram and angle	Distance, circumference, area, volume, ratio, % stenosis, histogram and angle
M mode Measurement	Distance, time, slope, and heart rate	Distance, time, slope, and heart rate
Doppler Measurement	Time, heart rate, velocity, acceleration, trace, and RI	Time, heart rate, velocity, acceleration, trace, and RI
Annotations	ID, patient name, doctor's name, birthday (It can be automatically calculated when input age), age (It can be automatically calculated when input birthday), sex.	ID, patient name, doctor's name, birthday (It can be automatically calculated when input age), age (It can be automatically calculated when input birthday), sex.
Body Mark	130 types	130 types
USB Port	USB 2.0	USB 2.0

Display	TFT-LCD	TFT-LCD
Diagonal Size	12.1-inch	12.1-inch
View Angle	Horizontal: Θ xTyp.: 80°; Vertical: Θ yTyp.: 80°; see the figure below.	Horizontal: Θ xTyp.: 80°; Vertical: Θ yTyp.: 80°; see the figure below.
Pixel Number	1024*768	1024*768
Center Luminance of White	Typ.: 450 cd/m ²	Typ.: 450 cd/m ²
Contrast Ratio	Typ.: 700	Typ.: 700
Operating Voltage	100-240V	100 V-240 V~
Operating Frequency	50Hz-60Hz	50 Hz/60 Hz
Input Power	1.8A~0.8A	1.8A~0.8A
Capacity	6400 mAh	6400 mAh
Voltage	14.8 VDC	14.8 VDC
Average Working time	2 h	2 h
Maximum charging time	8 h	8 h
Cycle Life	300 times	300 times
Main unit dimension	335mm(13.0") (L) x155mm(6.1") (W) x350mm(13.7") (H)	335mm(13.0") (L)x155mm(6.1") (W) x350mm(13.7") (H)
Net weight	6.0 kg	7.1 kg

Evaluation of similarities and differences:

The Medisono MS55 Plus, P25 Expert, P12 Plus, and P11 Plus have similar intended use, functionality, similar technologies as well as safety and performance characteristics than the Sonoscape P60, Sonoscape P20, Sonoscape P15, and Sonoscape S8, respectively. The Medisono models P9 Plus and P3 Plus have similar intended use, functionality, similar technologies as well as safety and performance characteristics as the Chison Eco 5, Chison Eco 2 ultrasound systems respectively. There are no differences among the Medisono devices and the corresponding predicate devices except for device network connectivity as the Medisono devices are not intended to be connected to a network.

Conclusion:

The subject device has similar technological characteristics and has similar intended use and functionality as the predicate devices. There are no differences between the devices that affect the usage, safety and effectiveness, thus no new question is raised regarding the safety and effectiveness. The non-clinical performance test data and software verification and validation demonstrate that the Medisono MS55 Plus, P25 Expert, P12 Plus, P11 Plus, P9 Plus, P3 Plus performs comparably to and it is as safe and effective as the predicate devices. In accordance with the 21 CFR Part 807 and based on the information provided in this premarket notification, Medisono MS55, P25 Expert, P12 Plus, P11 Plus, P9 Plus, P3 Plus is substantially equivalent to the predicate that is currently marketed for the same intended use.