DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 23, 2017

MEDISONO, LLC
% Jorge Millan, Ph.D.
Regulatory Affairs Director
HIATEC
601 West 20 Street
HIALEAH FL 33010

Re: K163688
Trade/Device Name: MEDISONO Ultrasonic Diagnostic Imaging System, models P1, P3 and P10
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX
Dated: January 11, 2017
Received: January 12, 2017

Dear Dr. 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 (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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K163688

Device Name
MEDISONO Ultrasonic Diagnostic Imaging System, models P1, P3 and P10

Indications for Use *(Describe)*
The MEDISONO Ultraonic Diagnostic Imaging System models P1, P3 and P10, 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), Transrecta and Transvagina.

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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"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."

Diagnostic Ultrasound Indications for Use Form
P1 Ultrasonic Diagnostic Imaging System

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation						
Specific	B	M	PW	CW	Color	Combined (Specify) [1]	Other (Specify) [2][3]
Ophthalmic							
Fetal / Obstetrics	N	N				N	Note 1, Note 2
Abdominal	N	N				N	Note 1, Note 2
Intra-operative (Specify)							
Intra-operative (Neuro logical)							
Laparoscopic							
Pediatric	N	N					Note 1, Note 2
Small Organ (Specify) *	N	N					Note 1, Note 2
Neonatal Cephalic	N	N					Note 1, Note 2
Adult Cephalic							
Trans-rectal	N	N				N	Note 1, Note 2
Trans-vaginal	N	N				N	Note 1, Note 2
Trans-urethral							
Musculo-skeletal(**Conventional**)	N	N				N	Note 1, Note 2
Musculo-skeletal (**Superficial**)	N	N				N	Note 1, Note 2
Intravascular							
Other (Gynecology)	N	N				N	
Cardiac	N	N				N	Note 1, Note 2
Intravascular							
Peripheral vascular	N	N				N	Note 1, Note 2
Other (Urology)	N	N				N	Note 1, Note 2

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M

Note 1: This feature does not use contrast agent

Note 2: Needle guide bracket kit

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form
P1 with C361-1/C341 Transducer

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation						
Specific	B	M	PW	CW	Color	Combined (Specify) [1]	Other (Specify) [2][3]
Ophthalmic							
Fetal / Obstetrics	N	N				N	Note 1, Note 2
Abdominal	N	N				N	Note 1, Note 2
Intra-operative (Specify)							
Intra-operative (Neuro logical)							
Laparoscopic							
Pediatric	N	N				N	Note 1, Note 2
Small Organ (Specify) *							
Neonatal Cephalic							
Adult Cephalic							
Trans-rectal							
Trans-vaginal							
Trans-urethral							
Musculo-skeletal(**Conventional**)							
Musculo-skeletal (**Superficial**)							
Intravascular							
Other (Gynecology)	N	N				N	Note 1, Note 2
Cardiac							
Intravascular							
Peripheral vascular							
Other (Urology)	N	N				N	Note 1, Note 2

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M

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Note 2: Needle guide bracket kit

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form
P1 with C321-1 Transducer

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation						
Specific	B	M	PW	CW	Color	Combined (Specify) [1]	Other (Specify) [2][3]
Ophthalmic							
Fetal / Obstetrics	N	N				N	Note 1, Note 2
Abdominal	N	N				N	Note 1, Note 2
Intra-operative (Specify)							
Intra-operative (Neuro logical)							
Laparoscopic							
Pediatric	N	N				N	Note 1, Note 2
Small Organ (Specify) *							
Neonatal Cephalic							
Adult Cephalic							
Trans-rectal							
Trans-vaginal							
Trans-urethral							
Musculo-skeletal(**Conventional**)							
Musculo-skeletal (**Superficial**)							
Intravascular							
Other (Gynecology)	N	N				N	Note 1, Note 2
Cardiac	N	N				N	Note 1, Note 2
Intravascular							
Peripheral vascular							
Other (Urology)	N	N				N	Note 1, Note 2

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M

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Note 2: Needle guide bracket kit

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form
P1 with L741 Transducer

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation						
Specific	B	M	PW	CW	Color	Combined (Specify) [1]	Other (Specify) [2][3]
Ophthalmic							
Fetal / Obstetrics							
Abdominal							
Intra-operative (Specify)							
Intra-operative (Neuro logical)							
Laparoscopic							
Pediatric							
Small Organ (Specify) *	N	N				N	Note 1, Note 2
Neonatal Cephalic	N	N				N	Note 1, Note 2
Adult Cephalic							
Trans-rectal							
Trans-vaginal							
Trans-urethral							
Musculo-skeletal(**Conventional**)	N	N				N	Note 1, Note 2
Musculo-skeletal (**Superficial**)	N	N				N	Note 1, Note 2
Intravascular							
Other (Gynecology)							
Cardiac							
Intravascular							
Peripheral vascular	N	N				N	Note 1, Note 2
Other (Urology)	N	N				N	Note 1, Note 2

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M

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Note 2: Needle guide bracket kit

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form
P1 with E741 Transducer

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation						
Specific	B	M	PW	CW	Color	Combined (Specify) [1]	Other (Specify) [2][3]
Ophthalmic							
Fetal / Obstetrics							
Abdominal							
Intra-operative (Specify)							
Intra-operative (Neuro logical)							
Laparoscopic							
Pediatric							
Small Organ (Specify) *							
Neonatal Cephalic							
Adult Cephalic							
Trans-rectal	N	N				N	Note 1, Note 2
Trans-vaginal							
Trans-urethral							
Musculo-skeletal(**Conventional**)							
Musculo-skeletal (**Superficial**)							
Intravascular							
Other (Gynecology)							
Cardiac							
Intravascular							
Peripheral vascular							
Other (Urology)	N	N				N	Note 1, Note 2

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M

Note 1: This feature does not use contrast agent

Note 2: Needle guide bracket kit

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form
P1 with E611-1 Transducer

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation						
Specific	B	M	PW	CW	Color	Combined (Specify) [1]	Other (Specify) [2][3]
Ophthalmic							
Fetal / Obstetrics	N	N				N	Note 1, Note 2
Abdominal							
Intra-operative (Specify)							
Intra-operative (Neuro logical)							
Laparoscopic							
Pediatric							
Small Organ (Specify) *							
Neonatal Cephalic							
Adult Cephalic							
Trans-rectal							
Trans-vaginal	N	N				N	Note 1, Note 2
Trans-urethral							
Musculo-skeletal(**Conventional**)							
Musculo-skeletal (**Superficial**)							
Intravascular							
Other (Gynecology)	N	N				N	Note 1, Note 2
Cardiac							
Intravascular							
Peripheral vascular							
Other (Urology)	N	N				N	Note 1, Note 2

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Additional comments: Combined mode: B+M

Note 1: This feature does not use contrast agent

Note 2: Needle guide bracket kit

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form
P1 with E611-1 Transducer

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation						
Specific	B	M	PW	CW	Color	Combined (Specify) [1]	Other (Specify) [2][3]
Ophthalmic							
Fetal / Obstetrics	N	N				N	Note 1, Note 2
Abdominal							
Intra-operative (Specify)							
Intra-operative (Neuro logical)							
Laparoscopic							
Pediatric							
Small Organ (Specify) *							
Neonatal Cephalic							
Adult Cephalic							
Trans-rectal							
Trans-vaginal	N	N				N	Note 1, Note 2
Trans-urethral							
Musculo-skeletal(**Conventional**)							
Musculo-skeletal (**Superficial**)							
Intravascular							
Other (Gynecology)	N	N				N	Note 1, Note 2
Cardiac							
Intravascular							
Peripheral vascular							
Other (Urology)	N	N				N	Note 1, Note 2

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Additional comments: Combined mode: B+M

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Note 2: Needle guide bracket kit

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form
P3 Ultrasonic Diagnostic Imaging System

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation						
Specific	B	M	PW	CW	Color	Combined (Specify) [1]	Other (Specify) [2][3]
Ophthalmic							
Fetal / Obstetrics	N	N	N			N	Note 1
Abdominal	N	N	N			N	Note 1
Intra-operative (Specify)							
Intra-operative (Neuro logical)							
Laparoscopic							
Pediatric	N	N	N			N	Note 1
Small Organ (Specify) *	N	N	N			N	Note 1
Neonatal Cephalic	N	N	N			N	Note 1
Adult Cephalic							
Trans-rectal	N	N	N			N	Note 1
Trans-vaginal	N	N	N			N	Note 1
Trans-urethral							
Musculo-skeletal(**Conventional**)	N	N	N			N	Note 1
Musculo-skeletal (**Superficial**)	N	N	N			N	Note 1
Intravascular							
Other (Gynecology)							
Cardiac	N	N	N			N	Note 1
Intravascular							
Peripheral vascular	N	N	N			N	Note 1
Other (Urology)	N	N	N			N	Note 1

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M

Note 1: This feature does not use contrast agent

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form
P3 with C363UA Transducer

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation						
Specific	B	M	PW	CW	Color	Combined (Specify) [1]	Other (Specify) [2][3]
Ophthalmic							
Fetal / Obstetrics	N	N	N			N	Note 1
Abdominal	N	N	N			N	Note 1
Intra-operative (Specify)							
Intra-operative (Neuro logical)							
Laparoscopic							
Pediatric	N	N	N			N	Note 1
Small Organ (Specify) *							
Neonatal Cephalic							
Adult Cephalic							
Trans-rectal							
Trans-vaginal							
Trans-urethral							
Musculo-skeletal(**Conventional**)							
Musculo-skeletal (**Superficial**)							
Intravascular							
Other (Gynecology)							
Cardiac							
Intravascular							
Peripheral vascular							
Other (Urology)	N	N	N			N	Note 1

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Additional comments: Combined mode: B+M

Note 1: This feature does not use contrast agent

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form
P3 with C362UA Transducer

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation						
Specific	B	M	PW	CW	Color	Combined (Specify) [1]	Other (Specify) [2][3]
Ophthalmic							
Fetal / Obstetrics	N	N	N			N	Note 1
Abdominal	N	N	N			N	Note 1
Intra-operative (Specify)							
Intra-operative (Neuro logical)							
Laparoscopic							
Pediatric	N	N	N			N	Note 1
Small Organ (Specify) *							
Neonatal Cephalic							
Adult Cephalic							
Trans-rectal							
Trans-vaginal							
Trans-urethral							
Musculo-skeletal(**Conventional**)							
Musculo-skeletal (**Superficial**)							
Intravascular							
Other (Gynecology)							
Cardiac							
Intravascular							
Peripheral vascular							
Other (Urology)	N	N	N			N	Note 1

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Additional comments: Combined mode: B+M

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form
P3 with C343UA Transducer

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation						
Specific	B	M	PW	CW	Color	Combined (Specify) [1]	Other (Specify) [2][3]
Ophthalmic							
Fetal / Obstetrics	N	N	N			N	Note 1
Abdominal	N	N	N			N	Note 1
Intra-operative (Specify)							
Intra-operative (Neuro logical)							
Laparoscopic							
Pediatric	N	N	N			N	Note 1
Small Organ (Specify) *							
Neonatal Cephalic							
Adult Cephalic							
Trans-rectal							
Trans-vaginal							
Trans-urethral							
Musculo-skeletal(**Conventional**)							
Musculo-skeletal (**Superficial**)							
Intravascular							
Other (Gynecology)							
Cardiac							
Intravascular							
Peripheral vascular							
Other (Urology)	N	N	N			N	Note 1

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Additional comments: Combined mode: B+M

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form
P3 with C321UA Transducer

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation						
Specific	B	M	PW	CW	Color	Combined (Specify) [1]	Other (Specify) [2][3]
Ophthalmic							
Fetal / Obstetrics							
Abdominal							
Intra-operative (Specify)							
Intra-operative (Neuro logical)							
Laparoscopic							
Pediatric	N	N	N			N	Note 1
Small Organ (Specify) *							
Neonatal Cephalic	N	N	N			N	Note 1
Adult Cephalic							
Trans-rectal							
Trans-vaginal							
Trans-urethral							
Musculo-skeletal(**Conventional**)							
Musculo-skeletal (**Superficial**)							
Intravascular							
Other (Gynecology)							
Cardiac	N	N	N			N	Note 1
Intravascular							
Peripheral vascular							
Other (Urology)	N	N	N			N	Note 1

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form
P3 with L743UA Transducer

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation						
Specific	B	M	PW	CW	Color	Combined (Specify) [1]	Other (Specify) [2][3]
Ophthalmic							
Fetal / Obstetrics							
Abdominal							
Intra-operative (Specify)							
Intra-operative (Neuro logical)							
Laparoscopic							
Pediatric							
Small Organ (Specify) *	N	N	N			N	Note 1
Neonatal Cephalic							
Adult Cephalic							
Trans-rectal							
Trans-vaginal							
Trans-urethral							
Musculo-skeletal(**Conventional**)	N	N	N			N	Note 1
Musculo-skeletal (**Superficial**)	N	N	N			N	Note 1
Intravascular							
Other (Gynecology)							
Cardiac							
Intravascular							
Peripheral vascular	N	N	N			N	Note 1
Other (Urology)							

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Additional comments: Combined mode: B+M

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form
P3 with L742UA Transducer

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation						
Specific	B	M	PW	CW	Color	Combined (Specify) [1]	Other (Specify) [2][3]
Ophthalmic							
Fetal / Obstetrics							
Abdominal							
Intra-operative (Specify)							
Intra-operative (Neuro logical)							
Laparoscopic							
Pediatric							
Small Organ (Specify) *	N	N	N			N	Note 1
Neonatal Cephalic							
Adult Cephalic							
Trans-rectal							
Trans-vaginal							
Trans-urethral							
Musculo-skeletal(**Conventional**)	N	N	N			N	Note 1
Musculo-skeletal (**Superficial**)	N	N	N			N	Note 1
Intravascular							
Other (Gynecology)							
Cardiac							
Intravascular							
Peripheral vascular	N	N				N	Note 1
Other (Urology)							

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form
P3 with L742UA Transducer

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation						
Specific	B	M	PW	CW	Color	Combined (Specify) [1]	Other (Specify) [2][3]
Ophthalmic							
Fetal / Obstetrics							
Abdominal							
Intra-operative (Specify)							
Intra-operative (Neuro logical)							
Laparoscopic							
Pediatric							
Small Organ (Specify) *	N	N	N			N	Note 1
Neonatal Cephalic							
Adult Cephalic							
Trans-rectal							
Trans-vaginal							
Trans-urethral							
Musculo-skeletal(**Conventional**)	N	N	N			N	Note 1
Musculo-skeletal (**Superficial**)	N	N	N			N	Note 1
Intravascular							
Other (Gynecology)							
Cardiac							
Intravascular							
Peripheral vascular	N	N				N	Note 1
Other (Urology)							

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M

Note 1: This feature does not use contrast agent

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form
P3 with L763UA Transducer

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation						
Specific	B	M	PW	CW	Color	Combined (Specify) [1]	Other (Specify) [2][3]
Ophthalmic							
Fetal / Obstetrics							
Abdominal							
Intra-operative (Specify)							
Intra-operative (Neuro logical)							
Laparoscopic							
Pediatric							
Small Organ (Specify) *	N	N	N			N	Note 1
Neonatal Cephalic							
Adult Cephalic							
Trans-rectal							
Trans-vaginal							
Trans-urethral							
Musculo-skeletal(**Conventional**)	N	N	N			N	Note 1
Musculo-skeletal (**Superficial**)	N	N	N			N	Note 1
Intravascular							
Other (Gynecology)							
Cardiac							
Intravascular							
Peripheral vascular	N	N				N	Note 1
Other (Urology)							

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Additional comments: Combined mode: B+M

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form
P3 with L743UA Transducer

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation						
Specific	B	M	PW	CW	Color	Combined (Specify) [1]	Other (Specify) [2][3]
Ophthalmic							
Fetal / Obstetrics							
Abdominal							
Intra-operative (Specify)							
Intra-operative (Neuro logical)							
Laparoscopic							
Pediatric							
Small Organ (Specify) *							
Neonatal Cephalic							
Adult Cephalic							
Trans-rectal	N	N	N			N	Note 1
Trans-vaginal							
Trans-urethral							
Musculo-skeletal(**Conventional**)							
Musculo-skeletal (**Superficial**)							
Intravascular							
Other (Gynecology)							
Cardiac							
Intravascular							
Peripheral vascular							
Other (Urology)	N	N				N	Note 1

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M

Note 1: This feature does not use contrast agent

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form
P3 with L613UA Transducer

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation						
Specific	B	M	PW	CW	Color	Combined (Specify) [1]	Other (Specify) [2][3]
Ophthalmic							
Fetal / Obstetrics							
Abdominal							
Intra-operative (Specify)							
Intra-operative (Neuro logical)							
Laparoscopic							
Pediatric	N	N	N			N	Note 1
Small Organ (Specify) *							
Neonatal Cephalic							
Adult Cephalic							
Trans-rectal							
Trans-vaginal							
Trans-urethral							
Musculo-skeletal(**Conventional**)							
Musculo-skeletal (**Superficial**)							
Intravascular							
Other (Gynecology)							
Cardiac	N	N	N			N	Note 1
Intravascular							
Peripheral vascular							
Other (Urology)							

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M

Note 1: This feature does not use contrast agent

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form
P10 Ultrasonic Diagnostic Imaging System

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation						
Specific	B	M	PW	CW	Color	Combined (Specify) [1]	Other (Specify) [2][3]
Ophthalmic							
Fetal / Obstetrics	N	N	N		N	N	Note 1, Note 2
Abdominal	N	N	N		N	N	Note 1, Note 2
Intra-operative (Specify)							
Intra-operative (Neuro logical)							
Laparoscopic							
Pediatric	N	N	N		N	N	Note 1, Note 2
Small Organ (Specify) *	N	N	N		N	N	Note 1, Note 2
Neonatal Cephalic	N	N					Note 1, Note 2
Adult Cephalic							
Trans-rectal							Note 1, Note 2
Trans-vaginal	N	N	N		N	N	Note 1, Note 2
Trans-urethral							
Musculo-skeletal(**Conventional**)	N	N	N		N	N	Note 1, Note 2
Musculo-skeletal (**Superficial**)	N	N	N		N	N	Note 1, Note 2
Intravascular							
Other (Specify**)	N	N	N		N	N	
Adult Cardiac	N	N	N		N	N	Note 1, Note 2
Pediatric Cardiac	N	N			N	N	Note 1, Note 2
Intravascular							
Peripheral vascular	N	N			N	N	Note 1, Note 2
Other (Urology)							

N = new indication; P = previously cleared by FDA; E = added under this appendix. PDI=Power Doppler Imaging.

Additional comments: Combined mode: B+M, B+PW, B+Color, B+PDI/DPDI, B+Color+PW, B+PDI/DPDI+PW

*Small organ includes Thyroid, Testes, Breast

**Other use includes Urology, Kidney, Gynecology

Note 1: Biopsy guide

Note 2: Harmonic imaging. This feature does not use contrast agent

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form
P10 with C352UB Transducer

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation						
Specific	B	M	PW	CW	Color	Combined (Specify) [1]	Other (Specify) [2][3]
Ophthalmic							
Fetal / Obstetrics	N	N	N		N	N	Note 1, Note 2
Abdominal	N	N	N		N	N	Note 1, Note 2
Intra-operative (Specify)							
Intra-operative (Neuro logical)							
Laparoscopic							
Pediatric							
Small Organ (Specify) *							
Neonatal Cephalic							
Adult Cephalic							
Trans-rectal							
Trans-vaginal							
Trans-urethral							
Musculo-skeletal(**Conventional**)							
Musculo-skeletal (**Superficial**)							
Intravascular							
Other (Specify**)	N	N	N		N	N	Note 1, Note 2
Adult Cardiac							
Pediatric Cardiac							
Intravascular							
Peripheral vascular							
Other (Urology)							

N= new indication; P = previously cleared by FDA; E = added under this appendix. PDI=Power Doppler Imaging.

Additional comments: Combined mode: B+M, B+PW, B+Color, B+PDI/DPDI, B+Color+PW, B+PDI/DPDI+PW

*Small organ includes Thyroid, Testes, Breast

**Other use includes Urology, Kidney, Gynecology

Note 1: Biopsy guide

Note 2: Harmonic imaging. This feature does not use contrast agent

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form
P10 with L1042UB Transducer

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation						
Specific	B	M	PW	CW	Color	Combined (Specify) [1]	Other (Specify) [2][3]
Ophthalmic							
Fetal / Obstetrics							
Abdominal							
Intra-operative (Specify)							
Intra-operative (Neuro logical)							
Laparoscopic							
Pediatric							
Small Organ (Specify) *	N	N	N		N	N	Note 1, Note 2
Neonatal Cephalic							
Adult Cephalic							
Trans-rectal							
Trans-vaginal							
Trans-urethral							
Musculo-skeletal(**Conventional**)	N	N	N		N	N	Note 1, Note 2
Musculo-skeletal (**Superficial**)	N	N	N		N	N	Note 1, Note 2
Intravascular							
Other (Specify**)							
Adult Cardiac							
Pediatric Cardiac							
Intravascular							
Peripheral vascular	N	N	N		N	N	Note 1, Note 2
Other (Urology)							

N= new indication; P = previously cleared by FDA; E = added under this appendix. PDI=Power Doppler Imaging.

Additional comments: Combined mode: B+M, B+PW, B+Color, B+PDI/DPDI, B+Color+PW, B+PDI/DPDI+PW

*Small organ includes Thyroid, Testes, Breast

**Other use includes Urology, Kidney, Gynecology

Note 1: Biopsy guide

Note 2: Harmonic imaging. This feature does not use contrast agent

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form
P10 with L742UB Transducer

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation						
Specific	B	M	PW	CW	Color	Combined (Specify) [1]	Other (Specify) [2][3]
Ophthalmic							
Fetal / Obstetrics							
Abdominal							
Intra-operative (Specify)							
Intra-operative (Neuro logical)							
Laparoscopic							
Pediatric							
Small Organ (Specify) *	N	N	N		N	N	Note 1, Note 2
Neonatal Cephalic							
Adult Cephalic							
Trans-rectal							
Trans-vaginal							
Trans-urethral							
Musculo-skeletal(**Conventional**)	N	N	N		N	N	Note 1, Note 2
Musculo-skeletal (**Superficial**)							
Intravascular	N	N	N		N	N	Note 1, Note 2
Other (Specify**)							
Adult Cardiac							
Pediatric Cardiac							
Intravascular							
Peripheral vascular	N	N	N		N	N	Note 1, Note 2
Other (Urology)							

N= new indication; P = previously cleared by FDA; E = added under this appendix. PDI=Power Doppler Imaging.

Additional comments: Combined mode: B+M, B+PW, B+Color, B+PDI/DPDI, B+Color+PW, B+PDI/DPDI+PW

*Small organ includes Thyroid, Testes, Breast

**Other use includes Urology, Kidney, Gynecology

Note 1: Biopsy guide

Note 2: Harmonic imaging. This feature does not use contrast agent

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form
P10 with E612UB Transducer

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation						
Specific	B	M	PW	CW	Color	Combined (Specify) [1]	Other (Specify) [2][3]
Ophthalmic							
Fetal / Obstetrics							
Abdominal							
Intra-operative (Specify)							
Intra-operative (Neuro logical)							
Laparoscopic							
Pediatric							
Small Organ (Specify) *							
Neonatal Cephalic							
Adult Cephalic							
Trans-rectal							
Trans-vaginal	N	N	N		N	N	Note 1, Note 2
Trans-urethral							
Musculo-skeletal(**Conventional**)							
Musculo-skeletal (**Superficial**)							
Intravascular							
Other (Specify**)							
Adult Cardiac							
Pediatric Cardiac							
Intravascular							
Peripheral vascular							
Other (Urology)							

N= new indication; P = previously cleared by FDA; E = added under this appendix. PDI=Power Doppler Imaging.

Additional comments: Combined mode: B+M, B+PW, B+Color, B+PDI/DPDI, B+Color+PW, B+PDI/DPDI+PW

*Small organ includes Thyroid, Testes, Breast

**Other use includes Urology, Kidney, Gynecology

Note 1: Biopsy guide

Note 2: Harmonic imaging. This feature does not use contrast agent

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form
P10 with C612UB Transducer

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation						
Specific	B	M	PW	CW	Color	Combined (Specify) [1]	Other (Specify) [2][3]
Ophthalmic							
Fetal / Obstetrics							
Abdominal							
Intra-operative (Specify)							
Intra-operative (Neuro logical)							
Laparoscopic							
Pediatric	N	N	N		N	N	Note 1, Note 2
Small Organ (Specify) *							
Neonatal Cephalic							
Adult Cephalic							
Trans-rectal							
Trans-vaginal							
Trans-urethral							
Musculo-skeletal(**Conventional**)							
Musculo-skeletal (**Superficial**)							
Intravascular							
Other (Specify**)							
Adult Cardiac							
Pediatric Cardiac	N	N	N		N	N	Note 1, Note 2
Intravascular							
Peripheral vascular							
Other (Urology)							

N= new indication; P = previously cleared by FDA; E = added under this appendix. PDI=Power Doppler Imaging.

Additional comments: Combined mode: B+M, B+PW, B+Color, B+PDI/DPDI, B+Color+PW, B+PDI/DPDI+PW

*Small organ includes Thyroid, Testes, Breast

**Other use includes Urology, Kidney, Gynecology

Note 1: Biopsy guide

Note 2: Harmonic imaging. This feature does not use contrast agent

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form
P10 with C6152UB Transducer

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation						
Specific	B	M	PW	CW	Color	Combined (Specify) [1]	Other (Specify) [2][3]
Ophthalmic							
Fetal / Obstetrics							
Abdominal							
Intra-operative (Specify)							
Intra-operative (Neuro logical)							
Laparoscopic							
Pediatric	N	N	N		N	N	Note 1, Note 2
Small Organ (Specify) *							
Neonatal Cephalic							
Adult Cephalic							
Trans-rectal							
Trans-vaginal							
Trans-urethral							
Musculo-skeletal(**Conventional**)							
Musculo-skeletal (**Superficial**)							
Intravascular							
Other (Specify**)							
Adult Cardiac							
Pediatric Cardiac	N	N	N		N	N	Note 1, Note 2
Intravascular							
Peripheral vascular							
Other (Urology)							

N= new indication; P = previously cleared by FDA; E = added under this appendix. PDI=Power Doppler Imaging.

Additional comments: Combined mode: B+M, B+PW, B+Color, B+PDI/DPDI, B+Color+PW, B+PDI/DPDI+PW

*Small organ includes Thyroid, Testes, Breast

**Other use includes Urology, Kidney, Gynecology

Note 1: Biopsy guide

Note 2: Harmonic imaging. This feature does not use contrast agent

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form
P10 with C422UB Transducer

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation						
Specific	B	M	PW	CW	Color	Combined (Specify) [1]	Other (Specify) [2][3]
Ophthalmic							
Fetal / Obstetrics							
Abdominal	N	N	N		N	N	Note 1, Note 2
Intra-operative (Specify)							
Intra-operative (Neuro logical)							
Laparoscopic							
Pediatric							
Small Organ (Specify) *							
Neonatal Cephalic							
Adult Cephalic							
Trans-rectal							
Trans-vaginal							
Trans-urethral							
Musculo-skeletal(**Conventional**)							
Musculo-skeletal (**Superficial**)							
Intravascular							
Other (Specify**)							
Adult Cardiac	N	N	N		N	N	Note 1, Note 2
Pediatric Cardiac							
Intravascular							
Peripheral vascular							
Other (Urology)							

N= new indication; P = previously cleared by FDA; E = added under this appendix. PDI=Power Doppler Imaging.

Additional comments: Combined mode: B+M, B+PW, B+Color, B+PDI/DPDI, B+Color+PW, B+PDI/DPDI+PW

*Small organ includes Thyroid, Testes, Breast

**Other use includes Urology, Kidney, Gynecology

Note 1: Biopsy guide

Note 2: Harmonic imaging. This feature does not use contrast agent

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form
P10 with L552UB Transducer

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation						
Specific	B	M	PW	CW	Color	Combined (Specify) [1]	Other (Specify) [2][3]
Ophthalmic							
Fetal / Obstetrics							
Abdominal							
Intra-operative (Specify)							
Intra-operative (Neuro logical)							
Laparoscopic							
Pediatric	N	N	N		N	N	Note 1, Note 2
Small Organ (Specify) *	N	N	N		N	N	Note 1, Note 2
Neonatal Cephalic							
Adult Cephalic							
Trans-rectal							
Trans-vaginal							
Trans-urethral							
Musculo-skeletal(**Conventional**)	N	N	N		N	N	Note 1, Note 2
Musculo-skeletal (**Superficial**)	N	N	N		N	N	Note 1, Note 2
Intravascular							
Other (Specify**)							
Adult Cardiac							
Pediatric Cardiac							
Intravascular							
Peripheral vascular	N	N	N		N	N	Note 1, Note 2
Other (Urology)							

N= new indication; P = previously cleared by FDA; E = added under this appendix. PDI=Power Doppler Imaging.

Additional comments: Combined mode: B+M, B+PW, B+Color, B+PDI/DPDI, B+Color+PW, B+PDI/DPDI+PW

*Small organ includes Thyroid, Testes, Breast

**Other use includes Urology, Kidney, Gynecology

Note 1: Biopsy guide

Note 2: Harmonic imaging. This feature does not use contrast agent

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Concurrence of CDRH, Office of Device Evaluation (ODE)

510K SUMMARY

MEDISONO Ultrasonic Diagnostic Imaging System

SUBMITTER MEDISONO, LLC
3511 SILVERSIDE RD STE 105
WILMINGTON, de 19810
Phone: 7864165587
Fax: 7864165587

US AGENT JORGE MILLAN, PHD
Official Correspondent for MEDISONO, LLC
601 WEST 20 St., HIALEAH, FL 33010
Email: jorgemillan4407@gmail.com
Web: https://www.sigmabiomedical.com

DEVICE NAME AND CLASSIFICATION

TRADE NAME: MEDISONO Ultrasonic Diagnostic Imaging System, models P1, P3 and P10

CLASSIFICATION NAME:
892.1550 System, Imaging, Pulsed Doppler, Ultrasonic
Product Code: IYN
892.1560 Ultrasonic, Pulsed Echo, Imaging
Product Code: IYO
892.1570 Transducer, Ultrasonic, Diagnostic
Product Code: ITX

REGULATORY CLASS: *Class II*
PANEL IDENTIFICATION *Radiology*

DEVICE DESCRIPTION

The P1 model is a portable digital ultrasonic diagnostic system applied in ultrasound diagnostic examination of abdominal, obstetrical, small parts, gynecological, orthopedic, cardiac, and urological 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 five display modes: B-Mode, 2B3-Mode, 4B3-Mode, M-Mode, B+M Mode. This system controlled by software is a Track 1 device that employs an array of probes that include linear array, convex linear array, microconvex linear array, transrectal and transvaginal with a frequency range of approximately 2.0M1Iz- 10.0MHz. The system consists of a main unit, transducers and other accessories.

The P3 model is a portable digital ultrasonic diagnostic system applied in ultrasound diagnostic examination of abdominal, obstetrical, small parts, gynecological, orthopedic, cardiac, and urological 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 the following display modes: B-Mode, M-Mode, B+M Mode and PW Mode. This system controlled by software is a Track 3 device that 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.OMHz-l0.OMHz. The system consists of a main unit, a display and transducers.

The P10 model is a portable Diagnostic Ultrasound System, which applies device advanced technologies such as Phased Inversion Harmonic Compound Imaging (eHCI), Multi-Beam-Forming (mBeam), Speckle Resistance Imaging (eSRI), and Spatial Compounding Imaging, etc. Various image parameter adjustments, 12.1 inch LCD and diverse probes are configured to provide clear and stable images. Its function is to acquire and display Ultrasound images in B-mode, M-mode, PW-mode, Color-mode, PDI/DPDI mode. This system provides a series of probes that include linear array, convex array, micro-convex array with a frequency range of approximately 2.5 MHz to 11 MHz.

Predicate Devices: The proposed system models are substantially equivalent to diagnostic ultrasound systems cleared for marketing in the US. The MEDISONO model P1 is equivalent to the D3, D6 ultrasound system (K122574); the P2 model is equivalent to the DUS 60 ultrasound system (K110999), and the P10 model is equivalent to the U50 ultrasound system (K123249). All diagnostic ultrasound systems and transducers are manufactured by EDAN Instruments Inc.

Indications for Use: The MEDISONO Ultrasonic Diagnostic Imaging System models P1, P3 and P10 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), Transrecta and Transvagina.

EFFECTIVENESS AND SAFETY CONSIDERATIONS

Clinical Test:
Clinical testing is not required.

Non-clinical Test:
The following safety standards are conducted on the subject device:

(1) IEC 60601-1 Medical Electrical Equipment Part 1: General Requirements for Safety and Essential Performance. 2012 A(2)
(2) 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: Nov, 2005
(3) IEC 60601-1-2 Medical Electrical Equipment – Part 1-2 General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Compatibility Requirements and Tests: March 2007
(4) Acoustic output testing as per the guideline "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers" dated September 9, 2008.
(5) ISO 10993-1 Biological Evaluation of Medical Devices – Tests for In Vitro Cytotoxicity: May, 1999
(6) ISO 10993-10 Biological Evaluation of Medical Devices – Part 10 -Tests for Irritation and Skin Sensitization: Aug, 2010
(7) ISO 14971 Medical Devices – Application of Risk Management to Medical Devices: March 1, 2007

COMPARISON TO PREDICATE DEVICE
The subject device has similar technology characteristics and has the same intended use, same design principle, same electrical classification, same manufacturing processes, materials and same accuracy. 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.

Substantially Equivalent Determination
The evaluation of the MEDISONO ultrasonic diagnostic imaging system does not raise any additional concerns regarding safety and effectiveness and may therefore be considered substantially equivalent to the predicate devices.