DEC 2 9 2011

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of safety and effectiveness is provided as part of this Premarket Notification in compliance with 21 CFR, Part 807, Subpart E, Section 807.92.

1. Submitter's Information: 21 CFR 807.92(a)(1)

SAMSUNG MEDISON CO., LTD.
1003, Daechi-dong, Gangnam-gu,
Seoul 135-280, Korea

Contact Person:
Kyeong-Mi, Park
Regulatory Affairs Manager

Telephone: 82.2.2194.1373
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Data Prepared: October 10, 2011

2. Name of the device:

Common/Usual Name:
Diagnostic Ultrasound System and Accessories
Proprietary Name:
MySono U6 Diagnostic Ultrasound System

Classification Names:	FR Number	Product Code
Ultrasonic Pulsed Doppler Imaging System	892.1550	IYN
Ultrasound Pulsed Echo Imaging System	892.1560	IYO
Diagnostic Ultrasound Transducer	892.1570	ITX

3. Identification of the predicate or legally marketed device:

- SONOACE R7 Diagnostic Ultrasound System (K112646)
- SONOACE X8 Diagnostic Ultrasound System (K093714)
- MySono U5 Diagnostic Ultrasound System (K100186)
- SONOACE R5 Diagnostic Ultrasound System (K103722)

4. Device Description:

The MySono U6 is a general purpose, hand-held, software controlled, diagnostic ultrasound system. Its function is to acquire ultrasound data and to display the data as B mode, M mode, Color Doppler imaging, Power Doppler imaging, PW/CW Spectral Doppler mode, Harmonic imaging, Tissue Doppler imaging, 3D imaging mode (real time 4D imaging mode) or as a combination of these modes. The MySono U6 also gives the operator the ability to measure anatomical structures and offers analysis packages that provide information that is used to make a diagnosis by competent health care professionals. The MySono U6 has real time acoustic output display with two basic indices, a mechanical index and a thermal index, which are both automatically displayed.

The MySono U6 has been designed to meet the following product safety standards:
- UL 60601-1, Safety requirements for Medical Equipment
- CSA C22.2 No. 601.1, Safety requirements for Medical Equipment
- IEC60601-2-37, Diagnostic Ultrasound Safety Standards
- IEC60601-1, Safety requirements for Medical Equipment
- IEC60601-1-2, EMC requirements for Medical Equipment
- NEMA UD-2, Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment
- NEMA UD-3, Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
- IEC 61157, Declaration of the acoustic output
- ISO10993-1, Biocompatibility

5. Intended Uses:

The MySono U6 Diagnostic Ultrasound System and transducers are intended for diagnostic ultrasound imaging and fluid analysis of the human body.

The clinical applications include: Fetal, Abdominal, Pediatric, Small Organs, Neonatal Cephalic, Adult Cephalic, Trans-rectal, Trans-vaginal, Muscular-Skeletal (Conventional, Superficial), Cardiac Adult, Cardiac Pediatric, Peripheral vessel.

6. Technological Characteristics:

The MySono U6 is substantially equivalent with respect to safety, effectiveness, and functionality to the SONOACE R7 Diagnostic Ultrasound System (K112646), SONOACE X8 Diagnostic Ultrasound System (K093714) , MySono U5 Diagnostic Ultrasound System (K100186), and SONOACE R5 Diagnostic Ultrasound System (K103722).
All systems transmit ultrasonic energy into patients, then perform post processing of received echoes to generate on-screen display of anatomic structures and fluid flow within the body. All system allow for specialized measurements of structures and flow, and calculations.

END of 510(K) Summary

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

DEC 2 9 2011

Samsung Medison Co., Ltd.
Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K113381
Trade/Device Name: MySono U6 Diagnostic Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, and ITX
Dated: December 19, 2011
Received: December 20, 2011

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we 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). 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.

This determination of substantial equivalence applies to the following transducers intended for use with the DUS 6000 Digital Ultrasonic Imaging System, as described in your premarket notification:

Transducer Model Number

C2-5	P2-4
C2-8	3DC2-6
C4-9	3D4-9
EVN4-9	CW2.0
LN5-12	

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. 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); 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.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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.

If you have any questions regarding the content of this letter, please contact Michael O'Hara at (301) 796-0294.

Sincerely Yours,

Mary S Pastel

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure(s)

SECTION 1.3
INDICATIONS FOR USE

510(k) Number (if known): _____

Device Name: MySono U6 Diagnostic Ultrasound System

Indications for Use:

The MySono U6 Diagnostic Ultrasound System and transducers are intended for diagnostic ultrasound imaging and fluid analysis of the human body.
The clinical applications include: Fetal, Abdominal, Pediatric, Small Organ, Neonatal Cephalic, Adult Cephalic, Trans-rectal, Trans-vaginal, Muscular-Skeletal (Conventional, Superficial), Cardiac Adult, Cardiac Pediatric, Peripheral vessel.

Prescription Use √ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Mary S. Pastel
(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K113381

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:
Device Name: MySono U6 Diagnostic Ultrasound System
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal *(See Note 3)*	N	N	N		N	Note 1	Notes 2, 4, 7, 8
	Abdominal	N	N	N	N	N	Note 1	Notes 2, 7, 8
	Intra-operative *(See Note 6)*							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	N	N	N		N	Note 1	Note 2, 5, 6, 7, 8
	Small Organ *(See Note 5)*	N	N	N		N	Note 1	Note 2, 5, 6, 7, 8
	Neonatal Cephalic	N	N	N		N	Note 1	Notes 8
	Adult Cephalic	N	N	N	N	N	Note 1	Note 7
	Trans-rectal	N	N	N		N	Note 1	Note 2, 7, 8
	Trans-vaginal	N	N	N		N	Note 1	Note 2, 7, 8
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)	N	N	N		N	Note 1	Note 2, 5, 6, 7
	Musculo-skel. (Superfic.)	N	N	N		N	Note 1	Note 2, 5, 6, 7
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult	N	N	N	N	N	Note 1	Note 4, 7
	Cardiac Pediatric	N	N	N	N	N	Note 1	Note 4, 7
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	N	N	N	N	N	Note 1	Note 2, 5, 6, 7, 8
	Other (spec.)							

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

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler
Note 1: B/M, B/Color M, B/PWD or CWD, B/Color Doppler, B/Color Doppler/PWD or CWD, B/Power Doppler/PWD, B/Color Doppler/Color M
Note 2: Includes imaging for guidance of biopsy
Note 3: Includes infertility monitoring of follicle development
Note 4: Color M-mode
Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients
Note 6: Abdominal organs and peripheral vessel
Note 7: Tissue Harmonic Imaging (THI)
Note 8: 3D imaging

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)
Prescription Use (Per 21 CFR 801.109)

Mary S. Pastel
(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K113381

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:
Device Name: C2-5 for use with MySono U6
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal *(See Note 3)*	P	P	P		P	Note 1	Notes 2, 4, 7, 8
	Abdominal	P	P	P		P	Note 1	Notes 2, 7, 8
	Intra-operative *(See Note 6)*							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note 1	Notes 2, 7, 8
	Small Organ *(See Note 5)*							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA K112646; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler
Note 1: B/M, B/Color M, B/PWD or CWD, B/Color Doppler, B/Color Doppler/PWD or CWD, B/Power Doppler/PWD, B/Color Doppler/Color M
Note 2: Includes imaging for guidance of biopsy
Note 3: Includes infertility monitoring of follicle development
Note 4: Color M-mode
Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients
Note 6: Abdominal organs and peripheral vessel
Note 7: Tissue Harmonic Imaging (THI)
Note 8: 3D imaging

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)
Prescription Use (Per 21 CFR 801.109)

Mary S Pastel

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K113381

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:
Device Name: C2-8 for use with MySono U6
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal *(See Note 3)*	P	P	P		P	Note 1	Notes 2, 4, 7, 8
	Abdominal	P	P	P		P	Note 1	Notes 2, 7, 8
	Intra-operative *(See Note 6)*							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note 1	Notes 2, 7, 8
	Small Organ *(See Note 5)*							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA K112646; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler
Note 1: B/M, B/Color M, B/PWD or CWD, B/Color Doppler, B/Color Doppler/PWD or CWD, B/Power Doppler/PWD, B/Color Doppler/Color M
Note 2: Includes imaging for guidance of biopsy
Note 3: Includes infertility monitoring of follicle development
Note 4: Color M-mode
Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients
Note 6: Abdominal organs and peripheral vessel
Note 7: Tissue Harmonic Imaging (THI)
Note 8: 3D imaging

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)
Prescription Use (Per 21 CFR 801.109)

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Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K113381

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:
Device Name: C4-9 for use with MySono U6
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal *(See Note 3)*	N	N	N		N	Note 1	Notes 8
	Abdominal	N	N	N		N	Note 1	Notes 8
	Intra-operative *(See Note 6)*							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	N	N	N		N	Note 1	Notes 8
	Small Organ *(See Note 5)*	N	N	N		N	Note 1	Notes 8
	Neonatal Cephalic	N	N	N		N	Note 1	Notes 8
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	Note 1	Notes 8
	Other (spec.)							

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

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler
Note 1: B/M, B/Color M, B/PWD or CWD, B/Color Doppler, B/Color Doppler/PWD or CWD, B/Power Doppler/PWD, B/Color Doppler/Color M
Note 2: Includes imaging for guidance of biopsy
Note 3: Includes infertility monitoring of follicle development
Note 4: Color M-mode
Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients
Note 6: Abdominal organs and peripheral vessel
Note 7: Tissue Harmonic Imaging (THI)
Note 8: 3D imaging

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)
Prescription Use (Per 21 CFR 801.109)

Mary S Pastel
(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K113381

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:
Device Name: EVN4-9 for use with MySono U6
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal *(See Note 3)*							
	Abdominal							
	Intra-operative *(See Note 6)*							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ *(See Note 5)*							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	P	P	P		P	Note 1	Notes 2, 8
	Trans-vaginal	P	P	P		P	Note 1	Notes 2, 8
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA K103722; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler
Note 1: B/M, B/Color M, B/PWD or CWD, B/Color Doppler, B/Color Doppler/PWD or CWD, B/Power Doppler/PWD, B/Color Doppler/Color M
Note 2: Includes imaging for guidance of biopsy
Note 3: Includes infertility monitoring of follicle development
Note 4: Color M-mode
Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients
Note 6: Abdominal organs and peripheral vessel
Note 7: Tissue Harmonic Imaging (THI)
Note 8: 3D imaging

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)
Prescription Use (Per 21 CFR 801.109)

Mary S Pastel
(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K113381

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:
Device Name: LN5-12 for use with MySono U6
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal *(See Note 3)*							
	Abdominal							
	Intra-operative *(See Note 6)*							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note 1	Notes 2,5,6,7
	Small Organ *(See Note 5)*	P	P	P		P	Note 1	Notes 2,5,6,7
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)	P	P	P		P	Note 1	Notes 2,5,6,7
	Musculo-skel. (Superfic.)	P	P	P		P	Note 1	Notes 2,5,6,7
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	Note 1	Notes 5,6,7
	Other (spec.)							

N= new indication; P= previously cleared by FDA K112646; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler
Note 1: B/M, B/Color M, B/PWD or CWD, B/Color Doppler, B/Color Doppler/PWD or CWD, B/Power Doppler/PWD, B/Color Doppler/Color M
Note 2: Includes imaging for guidance of biopsy
Note 3: Includes infertility monitoring of follicle development
Note 4: Color M-mode
Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients
Note 6: Abdominal organs and peripheral vessel
Note 7: Tissue Harmonic Imaging (THI)
Note 8: 3D imaging

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)
Prescription Use (Per 21 CFR 801.109)

Mary S Pastel

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K113381

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:
Device Name: P2-4 for use with MySono U6
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal (See Note 3)							
	Abdominal	P	P	P	P	P	Note 1	Note 7
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (See Note 5)							
	Neonatal Cephalic							
	Adult Cephalic	P	P	P	P	P	Note 1	Note 7
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult	P	P	P	P	P	Note 1	Note 4, 7
	Cardiac Pediatric	P	P	P	P	P	Note 1	Note 4, 7
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA K100186; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler
Note 1: B/M, B/Color M, B/PWD or CWD, B/Color Doppler, B/Color Doppler/PWD or CWD, B/Power Doppler/PWD, B/Color Doppler/Color M
Note 2: Includes imaging for guidance of biopsy
Note 3: Includes infertility monitoring of follicle development
Note 4: Color M-mode
Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients
Note 6: Abdominal organs and peripheral vessel
Note 7: Tissue Harmonic Imaging (THI)
Note 8: 3D imaging

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)
Prescription Use (Per 21 CFR 801.109)

Mary S Pastel
(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K113381

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:
Device Name: 3DC2-6 for use with MySono U6
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal *(See Note 3)*	P	P	P		P	Note 1	Note 2, 4, 7, 8
	Abdominal	P	P	P		P	Note 1	Note 2, 7, 8
	Intra-operative *(See Note 6)*							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note 1	Note 2, 7, 8
	Small Organ *(See Note 5)*							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA K112646; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler
Note 1: B/M, B/Color M, B/PWD or CWD, B/Color Doppler, B/Color Doppler/PWD or CWD, B/Power Doppler/PWD, B/Color Doppler/Color M
Note 2: Includes imaging for guidance of biopsy
Note 3: Includes infertility monitoring of follicle development
Note 4: Color M-mode
Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients
Note 6: Abdominal organs and peripheral vessel
Note 7: Tissue Harmonic Imaging (THI)
Note 8: 3D imaging

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)
Prescription Use (Per 21 CFR 801.109)

Mary S. Pastel
(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K113381

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:
Device Name: 3D4-9 for use with MySono U6
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal *(See Note 3)*							
	Abdominal							
	Intra-operative *(See Note 6)*							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ *(See Note 5)*							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	N	N	N		N	Note 1	Note 2, 7, 8
	Trans-vaginal	N	N	N		N	Note 1	Note 2, 7, 8
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

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

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler
Note 1: B/M, B/Color M, B/PWD or CWD, B/Color Doppler, B/Color Doppler/PWD or CWD, B/Power Doppler/PWD, B/Color Doppler/Color M
Note 2: Includes imaging for guidance of biopsy
Note 3: Includes infertility monitoring of follicle development
Note 4: Color M-mode
Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients
Note 6: Abdominal organs and peripheral vessel
Note 7: Tissue Harmonic Imaging (THI)
Note 8: 3D imaging

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)
Prescription Use (Per 21 CFR 801.109)

Mary S. Pastel
(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K113381

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:
Device Name: CW2.0 for use with MySono U6
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal *(See Note 3)*							
	Abdominal							
	Intra-operative *(See Note 6)*							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ *(See Note 5)*							
	Neonatal Cephalic							
	Adult Cephalic				P			
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult				P			
	Cardiac Pediatric				P			
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel				P			
	Other (spec.)							

N= new indication; P= previously cleared by FDA K093714; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler
Note 1: B/M, B/Color M, B/PWD or CWD, B/Color Doppler, B/Color Doppler/PWD or CWD, B/Power Doppler/PWD, B/Color Doppler/Color M
Note 2: Includes imaging for guidance of biopsy
Note 3: Includes infertility monitoring of follicle development
Note 4: Color M-mode
Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients
Note 6: Abdominal organs and peripheral vessel
Note 7: Tissue Harmonic Imaging (THI)
Note 8: 3D imaging

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)
Prescription Use (Per 21 CFR 801.109)

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