SEP 16 2011

K112451

Tab 19 PREMARKET NOTIFICATION 510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is:

Manufacturer:

SonoScape Company Limited

Address: 4/F., Yizhe Building, Yuquan Road,Nanshan, Shenzhen 518051, P.R.China

Tel: (86) 755-26722890

Fax: (86) 755-26722850

Contact Person: Chen Zhiqiang

Date Prepared: July 12, 2011

Name of the device:

*** Trade/Proprietary Name:**

S8 Diagnostic Ultrasound System

*** Common Name:** Diagnostic Ultrasound System and Transducers

*** Classification:**

Regulatory Class: II

Review Category: Tier II

21 CFR 892.1550 Ultrasonic Pulsed Doppler Imaging System (90-IYN)

21 CFR 892.1560 Ultrasonic Pulsed Echo Imaging System (90-IYO)

21 CFR 892.1570 Diagnostic Ultrasound Transducer (90-ITX)

Legally Marketed Predicate Device:

K092922, SonoScape S8 Diagnostic Ultrasound System

Device Description:

The SonoScape S8 Ultrasound System, previously cleared under K092922, is an integrated preprogrammed color ultrasound imaging system, capable of producing high detail resolution intended for clinical diagnostic imaging applications.

The only modifications that were made are:

The original S8 Diagnostic Ultrasound System, was previously cleared in K092922 dated March 12, 2009, uses an internal SMPS as its power supply system. And the proposed device was redesigned, changing from AC to battery power, i.e. the internal Li-ion Battery Pack (with an external AC adapter). Such a change is accompanied by labeling changes, but not including new indication for use (See Tab 3).

Table 21.1 lists the differences between the two power supply systems.

Table 21.1 Comparison of the Switching Mode Power Supply (SMPS) System and the Battery Pack Power Supply System

Model Item	S8 K092922 (with SMPS)	S8 TBD (with Battery Pack and AC Adapter)
Power supply	No battery pack is provided; The SMPS forms the power supply system.	An internal battery pack is provided; The power supply system consists of the AC adapter and DC converter and a Li-ion Battery Pack.
Working Principle of the Power Supply	The SMPS converts the 220V or 110V mains voltage to the DC voltages (+12V, -12V, +5V, +3.3V, +5VSB) required by all the electronic parts in the S8 Series System.	The AC adapter converts the mains voltage (100-240V AC) to a DC voltage of approximately +17.5V. Supplied with this DC voltage, the DC converter charges the battery and also converts the DC voltage to the lower voltages (+12V, -12V, +5V, +3.3V, +5VSB) required by all the electronic parts in the S8 system, and at the same time controls the LED indicators on the control panel/keyboard.

Model Item	S8 K092922 (with SMPS)	S8 TBD (with Battery Pack and AC Adapter)
Control Panel/ Keyboard	/	Compared to control panel of the original certified product, three LEDs have been added at the bottom right corner of the control panel.
Remarks	1) Since the original S8 System does not have internal battery, it requires the mains supply to operate. When no mains supply is provided, the system can not be turned on. 2) With the Li-ion Battery Pack, the S8 System can operate even when no mains supply is available.	

Intended Use:

The SonoScape S8 device is a general-purpose ultrasonic imaging instrument intended for use by a qualified physician for evaluation of Abdomen, Cardiac, Small Organ (breast, testes, thyroid), Peripheral Vascular, Musculo-skeletal (Conventional and Superficial), Pediatric, Fetal, Cephalic, OB/Gyn and Urology. This is the **same intended use** as previously cleared for the SonoScape S8 Diagnostic Ultrasound System, K092922.

Probe Information:

Tab 21.2 Probe information

No.	Probe	Type	Frequency Range	Intended Use
1	2P1	Phased Array	2.0-4.0 MHz	Abdominal Neonatal Cephalic Adult Cephalic Cardiac Adult Cardiac Pediatric
2	5P1	Phased Array	3.0-7.0 MHz	Pediatric Neonatal Cephalic Cardiac Pediatric
3	6V1	Micro-curved Array	4.0-8.0 MHz	Trans-rectal Trans-vaginal
4	6V3	Micro-curved Array	5.0-9.0 MHz	Trans-rectal Trans-vaginal
5	EC9-5	Micro-curved Array	5.0-9.0 MHz	Trans-rectal Trans-vaginal
6	C611	Micro-curved Array	4.0-8.0 MHz	Abdominal Pediatric Neonatal Cephalic Cardiac Pediatric

No.	Probe	Type	Frequency Range	Intended Use
7	C344	Curved Array	2.0-5.0 MHz	Fetal / Abdominal/ Ob/GYN
8	C362	Curved Array	2.0-6.0 MHz	Fetal / Abdominal/ Ob/GYN
9	VC6-2	Curved Array	2.0-6.0 MHz	Fetal / Abdominal/ Ob/GYN
10	L741	Linear Array	5.0-10.0 MHz	Small Organ (reast, thyroid, testes) Musculo-skeletal (Conventional) Peripheral vessel
11	L742	Linear Array	5.0-12.0 MHz	Small Organ (reast, thyroid, testes) Musculo-skeletal (Conventional) Musculo-skeletal (Superficial) Peripheral vessel
12	L743	Linear Array	5.0-10.0 MHz	Small Organ (reast, thyroid, testes) Musculo-skeletal (Conventional) Musculo-skeletal (Superficial) Peripheral vessel

Safety Considerations:

The S8 Diagnostic Ultrasound System incorporates the same fundamental technology as the predicate device. The device has been tested as Track 3 Device per the FDA Guidance document "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers" issued September 9, 2008. The acoustic output is measured and calculated per NEMA UD 2: 2004 Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment and NEMA UD3: 2004 Standards for Real-time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment. The device conforms to applicable medical device safety standards, such as IEC 60601-1, IEC 60601-1-1, IEC 60601-1-2, IEC 60601-2-37, ISO 10993-5 and ISO 10993-10.

Testing:

Laboratory testing was conducted to verify that the S8 Diagnostic Ultrasound System met all design specification and was substantially equivalent to the currently marketed Predicate Device as above. The device has been found to

conform to applicable medical device safety standards in regards to thermal, mechanical and electrical safety as well as biocompatibility. Acoustic output is measured and calculated according to "Acoustic Output Measuring Standard for Diagnostic Ultrasound Equipment".

Tab 21.3 Applicable Safety Standards

Standards No.	Standards Title	Version	Date
IEC 60601-1	IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995.	1988	10/31/2005
IEC 60601-1-2	IEC 60601-1-2, (Second Edition, 2001), Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility -- Requirements and Tests.	2007	07/31/2008
IEC 60601-2-37	IEC 60601-2-37 (2004) (2005) Amendment 2, Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment.	2007	09/08/2009
NEMA UD 2	NEMA UD 2-2004, Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment Version 3.	2004	09/08/2009
ISO 10993-5	ISO 10993-5:1999, Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity.	2009	09/12/2007
10993-10	ISO 10993-10:2002, Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity.	2002	09/12/2007

Conclusion:

The conclusions drawn from testing of the S8 Diagnostic Ultrasound System demonstrate that the device is as safe and effective as the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

SonoScape Company Limited
% Ms. Diana Hong
General Manager
Mid-Link Consulting Co., Ltd
P.O. Box 237-023
Shanghai, 200237
CHINA

SEP 16 2011

Re: K112451
Trade/Device Name: S8 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: August 24, 2011
Received: August 25, 2011

Dear Ms. Hong:

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 S8 Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

2P1 Phase Array	EC9-5 Micro-curved Array	VC6-2 Curved Array
5P1 Phase Array	C611 Micro-curved Array	L743 Linear Array
6V1 Micro-curved Array	C362 Curved Array	L741 Linear Array
6V3 Micro-curved Array	C344 Curved Array	L742 Linear Array

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 Shahram Vaezy, Ph.D. at (301) 796-6242.

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)

Tab 3 Indications For Use

510(k) Number:
Device Name: S8 Diagnostic Ultrasound System

Indications for Use: The SonoScape S8 device is a general-purpose ultrasonic imaging instrument intended for use by a qualified physician for evaluation of Abdomen, Cardiac, Small Organ (breast, testes, thyroid), Peripheral Vascular, Musculo-skeletal (Conventional and Superficial), Pediatric, Fetal, Cephalic, OB/Gyn and Urology.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 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

510(k) Number K112451

Diagnostic Ultrasound Indications for Use Form

System: **Sonoscape S8**
Diagnostic Ultrasound Pulsed Echo System
Diagnostic Ultrasound Pulsed Doppler Imaging System

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

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal Imaging& Other	Fetal	P	P	P		P	P	Note 1	Notes 2,4,5
	Abdominal	P	P	P		P	P	Note 1	Notes 2,4,5
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric	P	P	P		P	P	Note 1	Notes 2,4
	Small Organ (specify)	P	P	P		P	P	Note 1	Notes 2,4,6
	Neonatal Cephalic	P	P	P	P	P	P	Note 1	Notes 24
	Adult Cephalic	P	P	P	P	P	P	Note 1	Notes 2, 4
	Trans-rectal	P	P	P		P	P	Note 1	Notes 2
	Trans-vaginal	P	P	P		P	P	Note 1	Notes 2
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)	P	P	P		P	P	Note 1	Notes 2,4
	Musculo-skeletal (Superficial)	P	P	P		P	P	Note 1	Notes 2,4
	Intravascular								
	Other (Ob/GYN)	P	P	P		P	P	Note 1	Notes 2,4,5
Cardiac	Cardiac Adult	P	P	P	P	P	P	Note 1	Notes 2,3
	Cardiac Pediatric	P	P	P	P	P	P	Note 1	Notes 2,3
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral Vessel	Peripheral vessel	P	P	P		P	P	Note 1	Notes 2
	Other (specify)								

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

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M ; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging.

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

510K K112451

Diagnostic Ultrasound Indications for Use Form

Transducer: 2P1 Phase Array
Diagnostic Ultrasound Transducer

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

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal Imaging& Other	Fetal								
	Abdominal	P	P	P		P	P	Note 1	Notes 2
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic	P	P	P	P	P	P	Note 1	Notes 2
	Adult Cephalic	P	P	P	P	P	P	Note 1	Notes 2
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
Cardiac	Cardiac Adult	P	P	P	P	P	P	Note 1	Notes 2,3
	Cardiac Pediatric	P	P	P	P	P	P	Note 1	Notes 2,3
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral Vessel	Peripheral vessel								
	Other (specify)								

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

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M ; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging.

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

510K K112451

Diagnostic Ultrasound Indications for Use Form

Transducer: 5P1 Phase Array
Diagnostic Ultrasound Transducer

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

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal Imaging& Other	Fetal								
	Abdominal								
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric	P	P	P		P	P	Note 1	Notes 2
	Small Organ (specify)								
	Neonatal Cephalic	P	P	P	P	P	P	Note 1	Notes 2
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric	P	P	P	P	P	P	Note 1	Notes 2,3
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral Vessel	Peripheral vessel								
	Other (specify)								

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

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M ; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging.

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 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 K112457

Diagnostic Ultrasound Indications for Use Form

Transducer: 6V1 Micro-curved Array
Diagnostic Ultrasound Transducer

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

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal Imaging& Other	Fetal								
	Abdominal								
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal	P	P	P		P	P	Note 1	Notes 2
	Trans-vaginal	P	P	P		P	P	Note 1	Notes 2
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral Vessel	Peripheral vessel								
	Other (specify)								

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

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M ; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging.

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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Indications For Use 3-5

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Office of In Vitro Diagnostic Device Evaluation and Safety

510K K112151

Diagnostic Ultrasound Indications for Use Form

Transducer: 6V3 Micro-curved Array
Diagnostic Ultrasound Transducer

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

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal Imaging& Other	Fetal								
	Abdominal								
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal	P	P	P		P	P	Note 1	Notes 2
	Trans-vaginal	P	P	P		P	P	Note 1	Notes 2
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral Vessel	Peripheral vessel								
	Other (specify)								

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

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M ; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging.

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Indications For Use

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Office of In Vitro Diagnostic Device Evaluation and Safety

510K K112451

Diagnostic Ultrasound Indications for Use Form

Transducer: EC9-5 Micro-curved Array
Diagnostic Ultrasound Transducer

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

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal Imaging& Other	Fetal								
	Abdominal								
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal	P	P	P		P	P	Note 1	Notes 2
	Trans-vaginal	P	P	P		P	P	Note 1	Notes 2
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral Vessel	Peripheral vessel								
	Other (specify)								

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

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M ; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging.

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Indications For Use

Mary S Pastel 3-7
(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K112451

Diagnostic Ultrasound Indications for Use Form

Transducer: C611 Micro-curved Array
Diagnostic Ultrasound Transducer

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

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal Imaging& Other	Fetal								
	Abdominal	P	P	P		P	P	Note 1	Notes 2
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric	P	P	P		P	P	Note 1	Notes 2
	Small Organ (specify)								
	Neonatal Cephalic	P	P	P	P	P	P	Note 1	Notes 2
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric	P	P	P	P	P	P	Note 1	Notes 2,3
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral Vessel	Peripheral vessel								
	Other (specify)								

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

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M ; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging.

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Indications For Use

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510K K112451

Diagnostic Ultrasound Indications for Use Form

Transducer: C362 Curved Array
Diagnostic Ultrasound Transducer

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

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	P	P	P		P	P	Note 1	Notes 2,4
	Abdominal	P	P	P		P	P	Note1	Notes 2,4
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)	P	P	P		P	P	Note1	Notes 2,4
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral Vessel	Peripheral vessel								
	Other (specify)								

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

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M ; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging.

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Indications For Use

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

510K K112451

Diagnostic Ultrasound Indications for Use Form

Transducer: C344 Curved Array
Diagnostic Ultrasound Transducer

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

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal Imaging& Other	Fetal	P	P	P		P	P	Note 1	Notes 2, 4
	Abdominal	P	P	P		P	P	Note 1	Notes 2, 4
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)	P	P	P		P	P	Note 1	Notes 2, 4
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral Vessel	Peripheral vessel								
	Other (specify)								

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

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M ; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging.

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Indications For Use

3-10
(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K112151

Diagnostic Ultrasound Indications for Use Form

Transducer: VC6-2 Curved Array
Diagnostic Ultrasound Transducer

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

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	P	P	P		P	P	Note 1	Notes 2,4,5
	Abdominal	P	P	P		P	P	Note 1	Notes 2,4,5
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)	P	P	P		P	P	Note 1	Notes 2,4,5
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral Vessel	Peripheral vessel								
	Other (specify)								

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

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M ; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging.

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Indications For Use

Mary S Pastel 3-11
(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K112457

Diagnostic Ultrasound Indications for Use Form

Transducer: L743 Linear Array
Diagnostic Ultrasound Transducer

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

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal Imaging& Other	Fetal								
	Abdominal								
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)	P	P	P		P	P	Note 1	Notes 2, 4
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)	P	P	P		P	P	Note 1	Notes 2, 4
	Musculo-skeletal (Superficial)	P	P	P		P	P	Note 1	Notes 2, 4
	Intravascular								
	Other (Ob/GYN)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral Vessel	Peripheral vessel	P	P	P		P	P	Note 1	Notes 2, 4
	Other (specify)								

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

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M ; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging.

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

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

Indications For Use 3-12

510K K112451

Diagnostic Ultrasound Indications for Use Form

Transducer: L741 Linear Array
Diagnostic Ultrasound Transducer

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

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal Imaging& Other	Fetal								
	Abdominal								
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)	P	P	P		P	P	Note 1	Notes 2, 4
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)	P	P	P		P	P	Note 1	Notes 2, 4
	Musculo-skeletal (Superficial)	P	P	P		P	P	Note 1	Notes 2, 4
	Intravascular								
	Other (Ob/GYN)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral Vessel	Peripheral vessel	P	P	P		P	P	Note 1	Notes 2, 4
	Other (specify)								

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

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M ; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging.

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 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 K112451

Diagnostic Ultrasound Indications for Use Form

Transducer: L742 Linear Array
Diagnostic Ultrasound Transducer

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

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal Imaging& Other	Fetal								
	Abdominal								
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)	P	P	P		P	P	Note 1	Notes 2, 4
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)	P	P	P		P	P	Note 1	Notes 2, 4
	Musculo-skeletal (Superficial)	P	P	P		P	P	Note 1	Notes 2, 4
	Intravascular								
	Other (Ob/GYN)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral Vessel	Peripheral vessel	P	P	P		P	P	Note 1	Notes 2, 4
	Other (specify)								

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

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M ; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging.

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

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