K092922

PREMARKET NOTIFICATION 510(K) SUMMARY

MAR 12 2010

Trade Name: SonoScape Ultrasound System, S8™

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

Common Name: Diagnostic Ultrasound System

Classification Name: Ultrasonic Pulsed Echo Imaging System, 90 IYO

Manufacturer's Name: SonoScape Company Limited
4/F., Yizhe Building, Yuquan Road,
Nanshan, 518051, Shenzhen, China

Contact: Mr. Zhiqiang Chen, Vice-president
Telephone: (86) 755-26722890
Fax: (86) 755-26722850

U.S. Agent: Bob Leiker
Quality Regulatory Services, Inc.
Dublin, A 94568

Predicate Devices:

GE Voluson 730 Diagnostic Ultrasound System and Transducers – K003525

Shenzhen Mindray DC-7 Ultrasound - K092691

Device Description: The SonoScape S8 ultrasound system is an integrated preprogrammed color ultrasound imaging system, capable of producing high detail resolution intended for clinical diagnostic imaging applications.
The all digital architecture with progressive dynamic receive focusing allows the system to maximize the utility of all imaging transducers to enhance the diagnostic utility and confidence provided by the system. The exam dependent default setting allows the user to have minimum adjustment for imaging the patient, while the in-depth soft-menu control allows the advanced user to set the system for different situations. The architecture allows cost-effective system integration to a variety of upgrade-able options and features.

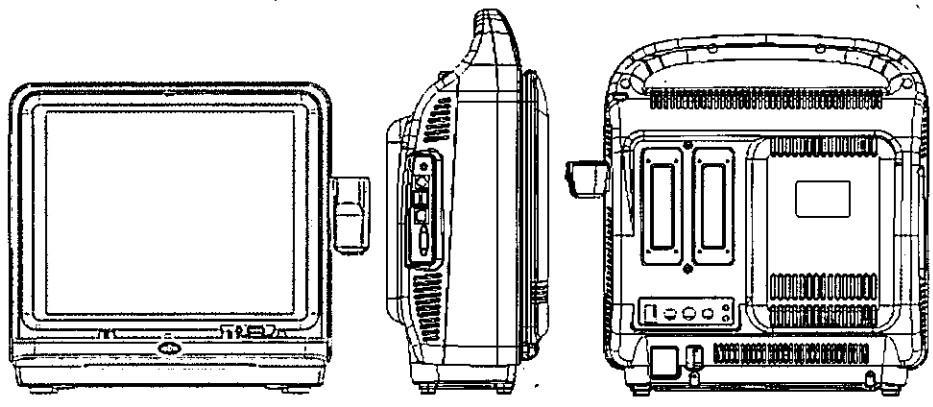
The SonoScape S8 System is configured as a portable model. The system is designed with the latest technology, using the same quality procedures as ultrasound systems, which have been available in the market for years.

This SonoScape system is a general purpose, software controlled, diagnostic ultrasound system. Its basic function is to acquire ultrasound data and display the image in B-Mode (including Tissue Harmonic Image), M-Mode, TDI, Color-Flow Doppler, Pulsed Doppler and Power Doppler, or a combination of these modes, 3D/4D.

The major features of the SonoScape S8:

- 64 Channel all digital beam former
- Progressive dynamic receive focusing
- Wide band all digital demodulation
- Native frequency digital scan converter
- S8 can be hand carried for portable use
- Remote access image management through LAN port
- USB2.0 flash drive for image transport and software upgrade
- Support for Phase array, Linear array, and Curve Linear array probes
- Based on Linux operating system
- Support 2D B-mode, M-mode, Harmonic Image, TDI, Color, Power Doppler, Pulse wave Doppler, CW and 3D/4D.

The S8 uses the LCD viewing monitor. The following drawings are provided for illustration;



S8

Intend Use: The 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), Heart soft tissue, Peripheral Vascular, Musculo-skeletal (Conventional and Superficial), Pediatric, Fetal, Cephalic, OB/Gyn and Urology.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

SonoScape Company Limited
% Mr. Bob Leiker
Quality & Regulatory Services
Leiker Regulatory & Quality Consulting
7263 Cronin Circle
DUBLIN CA 94568

MAR 12 2010

Re: K092922
Trade/Device Name: SonoScape 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: March 4, 2010
Received: March 8, 2010

Dear Mr. Leiker:

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

Transducer Model Number

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

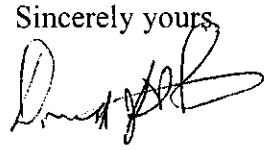
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 at (301) 796-6242.

Sincerely yours,



Donald J. St.Pierre
Acting 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 (if known): K092922

Device Name: SonoScape 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 _√_ AND/OR Over-The-Counter ____
(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)

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

510K K092922

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	N	N	N		N	N	Note 1	Notes 2, 4, 5
	Abdominal	N	N	N		N	N	Note 1	Notes 2,4,5
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric	N	N	N		N	N	Note 1	Notes 2,4
	Small Organ (specify)	N	N	N		N	N	Note 1	Notes 2,4,6
	Neonatal Cephalic	N	N	N	N	N	N	Note 1	Notes 2,4
	Adult Cephalic	N	N	N	N	N	N	Note 1	Notes 2,4
	Trans-rectal	N	N	N		N	N	Note 1	Notes 2
	Trans-vaginal	N	N	N		N	N	Note 1	Notes 2
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)	N	N	N		N	N	Note 1	Notes 2,4
	Musculo-skeletal (Superficial)	N	N	N		N	N	Note 1	Notes 2,4
	Intravascular								
	Other (Ob/GYN)	N	N	N		N	N	Note 1	Notes 2, 4, 5
Cardiac	Cardiac Adult	N	N	N	N	N	N	Note 1	Notes 2,3
	Cardiac Pediatric	N	N	N	N	N	N	Note 1	Notes 2,3
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	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 _√_ AND/OR Over-The-Counter ____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Office of In Vitro Diagnostic Device Evaluation and Safety

510K K092922

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	N	N	N		N	N	Note 1	Notes 2
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic	N	N	N	N	N	N	Note 1	Notes 2
	Adult Cephalic	N	N	N	N	N	N	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	N	N	N	N	N	N	Note 1	Notes 2,3
	Cardiac Pediatric	N	N	N	N	N	N	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 √ AND/OR Over-The-Counter ___
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

510K K092922

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	N	N	N		N	N	Note 1	Notes 2
	Small Organ (specify)								
	Neonatal Cephalic	N	N	N	N	N	N	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	N	N	N	N	N	N	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 √ AND/OR Over-The-Counter ___
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510K K092922

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	N	N	N		N	N	Note 1	Notes 2
	Trans-vaginal	N	N	N		N	N	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 √ AND/OR Over-The-Counter ____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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510K K092922

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	N	N	N		N	N	Note 1	Notes 2
	Trans-vaginal	N	N	N		N	N	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 √ AND/OR Over-The-Counter ____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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510K K092922

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	N	N	N		N	N	Note 1	Notes 2
	Trans-vaginal	N	N	N		N	N	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 √ AND/OR Over-The-Counter ____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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510K K092922

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	N	N	N		N	N	Note 1	Notes 2
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric	N	N	N		N	N	Note 1	Notes 2
	Small Organ (specify)								
	Neonatal Cephalic	N	N	N	N	N	N	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	N	N	N	N	N	N	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 √ AND/OR Over-The-Counter ___
(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)

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

510K K092922

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	N	N	N		N	N	Note 1	Notes 2,4
	Abdominal	N	N	N		N	N	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)	N	N	N		N	N	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 √ AND/OR Over-The-Counter ____
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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

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510K K092922

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	N	N	N		N	N	Note 1	Notes 2, 4
	Abdominal	N	N	N		N	N	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)	N	N	N		N	N	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 __√__ AND/OR Over-The-Counter ____
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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

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

510K K092922

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	N	N	N		N	N	Note 1	Notes 2,4,5
	Abdominal	N	N	N		N	N	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)	N	N	N		N	N	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 √ AND/OR Over-The-Counter ___
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510K K092922

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)	N	N	N		N	N	Note 1	Notes 2, 4
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)	N	N	N		N	N	Note 1	Notes 2, 4
	Musculo-skeletal (Superficial)	N	N	N		N	N	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	N	N	N		N	N	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 __√__ AND/OR Over-The-Counter ____
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510K K092992

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)	N	N	N		N	N	Note 1	Notes 2, 4
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)	N	N	N		N	N	Note 1	Notes 2, 4
	Musculo-skeletal (Superficial)	N	N	N		N	N	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	N	N	N		N	N	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 _√_ AND/OR Over-The-Counter ___
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510K K092922

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)	N	N	N		N	N	Note 1	Notes 2, 4
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)	N	N	N		N	N	Note 1	Notes 2, 4
	Musculo-skeletal (Superficial)	N	N	N		N	N	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	N	N	N		N	N	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 √ AND/OR Over-The-Counter ___
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