K122010

510(K) SUMMARY

JUL 20 2012

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(c).
The assigned 510(k) number is: _____.

1. Submitter:

Shenzhen Mindray Bio-medical Electronics Co., LTD
Mindray Building, Keji 12th Road South, Hi-tech Industrial Park, Nanshan, Shenzhen, 518057, P. R. China

Tel: +86 755 8188 5604
Fax: +86 755 2658 2680

Contact Person:
Zhai Pei
Shenzhen Mindray Bio-medical Electronics Co., LTD
Mindray Building, Keji 12th Road South, Hi-tech Industrial Park,
Nanshan, Shenzhen, 518057, P. R. China

Date Prepared: June 15, 2012

2. Device Name: Z6 Diagnostic Ultrasound System

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)

3. Device Description:

Z6 Diagnostic Ultrasound System is a general purpose, portable, software controlled, ultrasound diagnostic system. Its function is to acquire and display ultrasound images in B-Mode, M-Mode, PW-Mode, CW mode, Color-Mode, Power/Dirpower Mode, or the combined mode (i.e. B/M-Mode).This system is a Track 3 device that employs an array of probes that include linear array, convex array and phased array with a frequency range of approximately 2.5 MHz to 10.0 MHz.

4. Intended Use:

The Z6 Diagnostic Ultrasound System is applicable for adults, pregnant women, pediatric patients and neonates. It is intended for use in fetal, abdominal, intraoperative(abdominal, thoracic, and vascular), pediatric, small organ(breast, thyroid, testes), neonatal and adult cephalic, trans-rectal, trans-vaginal, musculo-skeletal(conventional, superficial), cardiac(adult, pediatric), peripheral vessel and urology exams.

5. Comparison with Predicate Devices:

Z6 Diagnostic Ultrasound System is comparable with and substantially equivalent to these predicate devices:

Predicate Device	Manufacturer	Model	510(k) Control Number
1	Mindray	M5	K102991,K083001
2	Mindray	M7	K100830
3	Mindray	DC-7	K103583
4	Mindray	DP-6900	K090912

They have the similar technological characteristics, are comparable in key safety and effectiveness features, and have the same intended uses and basic operating modes as the predicate devices.

6. Non-clinical Tests:

Z6 Diagnostic Ultrasound System has been evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness as well as thermal, electrical and mechanical safety, and has been found to conform with applicable medical safety standards. This device has been designed to meet the following standards: IEC 60601-1, IEC 60601-1-1, IEC 60601-1-2, IEC 60601-1-4, IEC 60601-2-37, IEC 62304, IEC 62366,UL 60601-1, ISO14971, UD 2, UD 3 and ISO 10993-1.

Conclusion:

Intended uses and other key features are consistent with traditional clinical practices, FDA guidelines and established methods of patient examination. The design, development and quality process of the manufacturer confirms with 21 CFR 820, ISO 9001 and ISO 13485 quality systems. The device conforms to applicable medical device safety standards. Therefore, the Z6 Diagnostic Ultrasound System is substantially equivalent with respect to safety and effectiveness to devices currently cleared for market.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

JUL 20 2012

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
% Mr. Jeff D. Rongero
Senior Project Manager
UL LLC
12 Laboratory Drive
RESEARCH TRIANGLE PARK NC 27709

Re: K122010
Trade/Device Name: Z6 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: June 29, 2012
Received: July 9, 2012

Dear Mr. Rongero:

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 Z6 Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

3C5P	CB10-4P
6C2P	V10-4BP
6CV1P	7LT4P
7L4P	6LE7P
7L5P	2P2P
L14-6P	

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 Jeffrey Ballyns at (301) 796-6105.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Indications for Use

510(k) Number (if known):

Device Name: Z6 Diagnostic Ultrasound System

Indications For Use:

The Z6 Diagnostic Ultrasound System is applicable for adults, pregnant women, pediatric patients and neonates. It's intended for use in fetal, abdominal, intraoperative (abdominal, thoracic, and vascular), pediatric, small organ (breast, thyroid, testes), neonatal and adult cephalic, trans-rectal, trans-vaginal, musculo-skeletal (conventional, superficial), cardiac (adult, pediatric), peripheral vessel and urology exams.

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

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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 k122810

mindray迈瑞

Diagnostic Ultrasound Indications for Use Form

System × Transducer _____

Model: Z6 Diagnostic Ultrasound System

510(k) Number(s) _____

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal	N	N	N		N	N	N	Note1,2
Abdominal	N	N	N	N	N	N	N	Note1,2
Intraoperative (specify)*	N	N	N		N	N	N	Note 1,2
Intraoperative (Neuro)								
Laparoscopic								
Pediatric	N	N	N	N	N	N	N	Note 1, 2
Small organ(specify)**	N	N	N		N	N	N	Note 1,2
Neonatal Cephalic	N	N	N	N	N	N	N	Note 1, 2
Adult Cephalic	N	N	N		N	N	N	Note1, 2
Trans-rectal	N	N	N		N	N	N	Note 1, 2
Trans-vaginal	N	N	N		N	N	N	Note 1, 2
Trans-urethral								
Trans-esoph.(non-Card.)								
Musculo-skeletal Conventional	N	N	N		N	N	N	Note 1,2
Musculo-skeletal Superficial	N	N	N		N	N	N	Note 1,2
Intravascular								
Cardiac Adult	N	N	N	N	N	N	N	Note 1,2
Cardiac Pediatric	N	N	N	N	N	N	N	Note 1,2
Intravascular (Cardiac)								
Trans-esoph.(Cardiac)								
Intra-Cardiac								
Peripheral Vessel	N	N	N		N	N	N	Note1, 2
Other (specify)***	N	N	N		N	N	N	Note 1, 2

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

Additional comments:Combined modes: B+M, PW+B, Color+B, Power+B, Color+B+PW, Power+B+PW

*Intraoperative includes abdominal, thoracic, and vascular

**Small organ-breast, thyroid, testes

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Biopsy Guidance

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation(ODE)

Prescription USE (Per 21 CFR 801.109)

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

510K K122010

Diagnostic Ultrasound Indications for Use Form

System ____ Transducer ×

Model: 3C5P

510(k) Number(s)

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal	N	N	N		N	N	N	Note 1, 2
Abdominal	N	N	N		N	N	N	Note 1, 2
Intraoperative (specify)*								
Intraoperative (Neuro)								
Laparoscopic								
Pediatric	N	N	N		N	N	N	Note 1, 2
Small organ(specify)**								
Neonatal Cephalic								
Adult Cephalic								
Trans-rectal								
Trans-vaginal								
Trans-urethral								
Trans-esoph.(non-Card.)								
Musculo-skeletal Conventional	N	N	N		N	N	N	Note 1, 2
Musculo-skeletal Superficial								
Intravascular								
Cardiac Adult								
Cardiac Pediatric								
Intravascular (Cardiac)								
Trans-esoph.(Cardiac)								
Intra-Cardiac								
Peripheral Vessel	N	N	N		N	N	N	Note 1, 2
Other (specify)***								

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

Additional comments:Combined modes: B+M, PW+B, Color+B, Power+B, Color+B+PW, Power+B+PW

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Concurrence of CDRH, Office of Device Evaluation(ODE)

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 2010

Diagnostic Ultrasound Indications for Use Form

System _____ Transducer ×

Model: 6C2P

510(k) Number(s) _____

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal								
Abdominal	N	N	N		N	N	N	Note 1, 2
Intraoperative (specify)*								
Intraoperative (Neuro)								
Laparoscopic								
Pediatric	N	N	N		N	N	N	Note 1, 2
Small organ(specify)**								
Neonatal Cephalic	N	N	N		N	N	N	Note 1, 2
Adult Cephalic	N	N	N		N	N	N	Note 1, 2
Trans-rectal								
Trans-vaginal								
Trans-urethral								
Trans-esoph.(non-Card.)								
Musculo-skeletal Conventional								
Musculo-skeletal Superficial								
Intravascular								
Cardiac Adult								
Cardiac Pediatric								
Intravascular (Cardiac)								
Trans-esoph.(Cardiac)								
Intra-Cardiac								
Peripheral Vessel								
Other (specify)***								

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

Additional comments:Combined modes: B+M, PW+B, Color+B, Power+B, Color+B+PW, Power+B+PW

*Intraoperative includes abdominal, thoracic, and vascular

**Small organ-breast, thyroid, testes

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Biopsy Guidance

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation(ODE)

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 5122010

Diagnostic Ultrasound Indications for Use Form

System: ____ Transducer: ×

Model: 6CV1P

510(k) Number(s):

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal	N	N	N		N	N	N	Note 1, 2
Abdominal								
Intraoperative (specify)*								
Intraoperative (Neuro)								
Laparoscopic								
Pediatric								
Small organ(specify)**								
Neonatal Cephalic								
Adult Cephalic								
Trans-rectal	N	N	N		N	N	N	Note 1, 2
Trans-vaginal	N	N	N		N	N	N	Note 1, 2
Trans-urethral								
Trans-esoph.(non-Card.)								
Musculo-skeletal Conventional								
Musculo-skeletal Superficial								
Intravascular								
Cardiac Adult								
Cardiac Pediatric								
Intravascular (Cardiac)								
Trans-esoph.(Cardiac)								
Intra-Cardiac								
Peripheral Vessel								
Other (specify)***	N	N	N		N	N	N	Note 1, 2

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

Additional comments:Combined modes: B+M, PW+B, Color+B, Power+B, Color+B+PW, Power+B+PW

*Intraoperative includes abdominal, thoracic, and vascular

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Note 2: Biopsy Guidance

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Concurrence of CDRH, Office of Device Evaluation(ODE)

Prescription USE (Per 21 CFR 801.109)

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Office of In Vitro Diagnostic Device Evaluation and Safety

510K 6122010

Diagnostic Ultrasound Indications for Use Form

System ____ Transducer ×

Model: 7L4P

510(k) Number(s) ____

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal								
Abdominal	N	N	N		N	N	N	Note 1,2
Intraoperative (specify)*								
Intraoperative (Neuro)								
Laparoscopic								
Pediatric	N	N	N		N	N	N	Note 1,2
Small organ(specify)**	N	N	N		N	N	N	Note 1,2
Neonatal Cephalic	N	N	N		N	N	N	Note 1,2
Adult Cephalic								
Trans-rectal								
Trans-vaginal								
Trans-urethral								
Trans-esoph.(non-Card.)								
Musculo-skeletal Conventional	N	N	N		N	N	N	Note 1,2
Musculo-skeletal Superficial	N	N	N		N	N	N	Note 1,2
Intravascular								
Cardiac Adult								
Cardiac Pediatric								
Intravascular (Cardiac)								
Trans-esoph.(Cardiac)								
Intra-Cardiac								
Peripheral Vessel	N	N	N		N	N	N	Note 1,2
Other (specify)***								

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

Additional comments:Combined modes: B+M, PW+B, Color+B, Power+B, Color+B+PW, Power+B+PW

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**Small organ-breast, thyroid, testes

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Biopsy Guidance

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Concurrence of CDRH, Office of Device Evaluation(ODE)

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 K122010

Diagnostic Ultrasound Indications for Use Form

System ____ Transducer ×

Model: 7L5P

510(k) Number(s) ____

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal								
Abdominal	N	N	N		N	N	N	Note 1,2
Intraoperative (specify)*								
Intraoperative (Neuro)								
Laparoscopic								
Pediatric	N	N	N		N	N	N	Note 1,2
Small organ(specify)**	N	N	N		N	N	N	Note 1,2
Neonatal Cephalic	N	N	N		N	N	N	Note 1,2
Adult Cephalic								
Trans-rectal								
Trans-vaginal								
Trans-urethral								
Trans-esoph.(non-Card.)								
Musculo-skeletal Conventional	N	N	N		N	N	N	Note 1,2
Musculo-skeletal Superficial	N	N	N		N	N	N	Note 1,2
Intravascular								
Cardiac Adult								
Cardiac Pediatric								
Intravascular (Cardiac)								
Trans-esoph.(Cardiac)								
Intra-Cardiac								
Peripheral Vessel	N	N	N		N	N	N	Note 1,2
Other (specify)***								

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

Additional comments:Combined modes: B+M, PW+B, Color+B, Power+B, Color+B+PW, Power+B+PW

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***Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Biopsy Guidance

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Concurrence of CDRH, Office of Device Evaluation(ODE)

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 5/22/2010

Diagnostic Ultrasound Indications for Use Form

System ____ Transducer ×

Model: L14-6P

510(k) Number(s)

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal								
Abdominal	N	N	N		N	N	N	Note 1,2
Intraoperative (specify)*								
Intraoperative (Neuro)								
Laparoscopic								
Pediatric	N	N	N		N	N	N	Note 1,2
Small organ(specify)**	N	N	N		N	N	N	Note 1,2
Neonatal Cephalic	N	N	N		N	N	N	Note 1,2
Adult Cephalic								
Trans-rectal								
Trans-vaginal								
Trans-urethral								
Trans-esoph.(non-Card.)								
Musculo-skeletal Conventional	N	N	N		N	N	N	Note 1,2
Musculo-skeletal Superficial	N	N	N		N	N	N	Note 1,2
Intravascular								
Cardiac Adult								
Cardiac Pediatric								
Intravascular (Cardiac)								
Trans-esoph.(Cardiac)								
Intra-Cardiac								
Peripheral Vessel	N	N	N		N	N	N	Note 1,2
Other (specify)***								

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

Additional comments:Combined modes: B+M, PW+B, Color+B, Power+B, Color+B+PW, Power+B+PW

*Intraoperative includes abdominal, thoracic, and vascular

**Small organ-breast, thyroid, testes

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Biopsy Guidance

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Concurrence of CDRH, Office of Device Evaluation(ODE)

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 K122010

Diagnostic Ultrasound Indications for Use Form

System ____ Transducer . ×

Model: CB10-4P

510(k) Number(s) _____

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal								
Abdominal								
Intraoperative (specify)*								
Intraoperative (Neuro)								
Laparoscopic								
Pediatric								
Small organ(specify)**								
Neonatal Cephalic								
Adult Cephalic								
Trans-rectal	N	N	N		N	N	N	Note 1,2
Trans-vaginal								
Trans-urethral								
Trans-esoph.(non-Card.)								
Musculo-skeletal Conventional								
Musculo-skeletal Superficial								
Intravascular								
Cardiac Adult								
Cardiac Pediatric								
Intravascular (Cardiac)								
Trans-esoph.(Cardiac)								
Intra-Cardiac								
Peripheral Vessel								
Other (specify)***	N	N	N		N	N	N	Note 1,2

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

Additional comments:Combined modes: B+M, PW+B, Color+B, Power+B, Color+B+PW, Power+B+PW

*Intraoperative includes abdominal, thoracic, and vascular

**Small organ-breast, thyroid, testes

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Biopsy Guidance

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Concurrence of CDRH, Office of Device Evaluation(ODE)

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 6122010

Diagnostic Ultrasound Indications for Use Form

System ____ Transducer ×

Model: V10-4BP

510(k) Number(s) _____

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal	N	N	N		N	N	N	Note 1, 2
Abdominal								
Intraoperative (specify)*								
Intraoperative (Neuro)								
Laparoscopic								
Pediatric								
Small organ(specify)**								
Neonatal Cephalic								
Adult Cephalic								
Trans-rectal	N	N	N		N	N	N	Note 1, 2
Trans-vaginal	N	N	N		N	N	N	Note 1, 2
Trans-urethral								
Trans-esoph.(non-Card.)								
Musculo-skeletal Conventional								
Musculo-skeletal Superficial								
Intravascular								
Cardiac Adult								
Cardiac Pediatric								
Intravascular (Cardiac)								
Trans-esoph.(Cardiac)								
Intra-Cardiac								
Peripheral Vessel								
Other (specify)***	N	N	N		N	N	N	Note 1, 2

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

Additional comments:Combined modes: B+M, PW+B, Color+B, Power+B, Color+B+PW, Power+B+PW

*Intraoperative includes abdominal, thoracic, and vascular

**Small organ-breast, thyroid, testes

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Biopsy Guidance

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation(ODE)

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 6122010

Diagnostic Ultrasound Indications for Use Form

System ____ Transducer ×

Model: 7LT4P

510(k) Number(s) _____

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal								
Abdominal	N	N	N		N	N	N	Note 1,2
Intraoperative (specify)*	N	N	N		N	N	N	Note 1,2
Intraoperative (Neuro)								
Laparoscopic								
Pediatric	N	N	N		N	N	N	Note 1,2
Small organ(specify)**	N	N	N		N	N	N	Note 1,2
Neonatal Cephalic	N	N	N		N	N	N	Note 1,2
Adult Cephalic								
Trans-rectal								
Trans-vaginal								
Trans-urethral								
Trans-esoph.(non-Card.)								
Musculo-skeletal Conventional	N	N	N		N	N	N	Note 1,2
Musculo-skeletal Superficial	N	N	N		N	N	N	Note 1,2
Intravascular								
Cardiac Adult								
Cardiac Pediatric								
Intravascular (Cardiac)								
Trans-esoph.(Cardiac)								
Intra-Cardiac								
Peripheral Vessel	N	N	N		N	N	N	Note 1,2
Other (specify)***								

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

Additional comments:Combined modes: B+M, PW+B, Color+B, Power+B, Color+B+PW, Power+B+PW

*Intraoperative includes abdominal, thoracic, and vascular

**Small organ-breast, thyroid, testes

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Biopsy Guidance

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Concurrence of CDRH, Office of Device Evaluation(ODE)

Prescription USE (Per 21 CFR 801.109)

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

510K 5122010

Diagnostic Ultrasound Indications for Use Form

System ____ Transducer ×

Model: 6LE7P

510(k) Number(s) ____

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal								
Abdominal								
Intraoperative (specify)*								
Intraoperative (Neuro)								
Laparoscopic								
Pediatric								
Small organ(specify)**								
Neonatal Cephalic								
Adult Cephalic								
Trans-rectal	N	N	N		N	N	N	Note 1,2
Trans-vaginal								
Trans-urethral								
Trans-esoph.(non-Card.)								
Musculo-skeletal Conventional								
Musculo-skeletal Superficial								
Intravascular								
Cardiac Adult								
Cardiac Pediatric								
Intravascular (Cardiac)								
Trans-esoph.(Cardiac)								
Intra-Cardiac								
Peripheral Vessel								
Other (specify)***	N	N	N		N	N	N	Note 1,2

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

Additional comments:Combined modes: B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular

**Small organ-breast, thyroid, testes

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Biopsy Guidance

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation(ODE)

Prescription USE (Per 21 CFR 801.109)

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

510K 6/22/2010

Diagnostic Ultrasound Indications for Use Form

System ____ Transducer ×

Model: 2P2P

510(k) Number(s) _____

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal								
Abdominal	N	N	N	N	N	N	N	Note 1,2
Intraoperative (specify)*								
Intraoperative (Neuro)								
Laparoscopic								
Pediatric	N	N	N	N	N	N	N	Note 1,2
Small organ(specify)**								
Neonatal Cephalic	N	N	N	N	N	N	N	Note 1,2
Adult Cephalic								
Trans-rectal								
Trans-vaginal								
Trans-urethral								
Trans-esoph.(non-Card.)								
Musculo-skeletal Conventional								
Musculo-skeletal Superficial								
Intravascular								
Cardiac Adult	N	N	N	N	N	N	N	Note 1,2
Cardiac Pediatric	N	N	N	N	N	N	N	Note 1,2
Intravascular (Cardiac)								
Trans-esoph.(Cardiac)								
Intra-Cardiac								
Peripheral Vessel								
Other (specify)***								

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

Additional comments:Combined modes: B+M, PW+B, Color+B, Power+B, Color+B+PW, Power+B+PW

*Intraoperative includes abdominal, thoracic, and vascular

**Small organ-breast, thyroid, testes

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note8: Biopsy Guidance

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation(ODE)

Prescription USE (Per 21 CFR 801.109)

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