K101041

510(K) SUMMARY

APR 30 2010

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 2658 2551
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Contact Person:
Meng Xianjun
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: Jan. 08, 2010

2. Device Name: DC-7 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. Marketed Device:

DC-7 Diagnostic Ultrasound System is substantially equivalent to the following devices: Mindray DC-7 (K#092691), Mindray DC-3 (K#091941), GE Logiq P5 (K#060993), GE Voluson 730 (K#041688).
Compared to the original submission (K#092691), the technological characteristics are almost identical in this submission except for the new features and indications such as

new probes, software functions, new algorithm and etc.
The only unique feature found on the DC-7 compared to the predicate devices is the calculation of the ABI(ankle-brachial index), this feature does not affect the safety or effectiveness of the device.

4. Device Description:

The DC-7 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, Color mode, Color M mode, PW mode, CW mode, Power/DirPower mode, TDI 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 probe, convex array probe, phased array probe and volume probe with a frequency range of approximately 1.8 MHz to 12.0 MHz.

5. Intended Use:

The DC-7 Diagnostic Ultrasound System is applicable for adults, pregnant women, pediatric patients and neonates. It is intended for use in abdominal, cardiac, small organ (breast, testes, thyroid, etc.), peripheral vascular, fetal, transrectal, transvaginal, pediatric, neonatal cephalic, musculoskeletal(conventional and superficial), intraoperative and transcranial exams.

6. Safety Considerations:

The DC-7 Diagnostic Ultrasound System had been tested as Track 3 Device per the FDA Guidance document "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers" issued in September 2008. The acoustic output is measured and calculated per NEMA UD 2: 2004 Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment and NEMA UD 3: 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, IEC 60601-1-4 and ISO 10993-1.

Conclusion:

The conclusions drawn from testing of the DC-7 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
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN 3 - 2010

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
% Mr. Robert Mosenkis
President
CITECH
5200 Butler Pike
Plymouth Meeting, PA 19462

Re: K101041
Trade/Device Name: DC-7 Diagnostic Ultrasound Systems
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, ITX, and IYO
Dated: April 13, 2010
Received: April 14, 2010

Dear Mr. Mosenkis:

This letter corrects our substantially equivalent letter of April 30, 2010.

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 DC-7 Diagnostic Ultrasound Systems, as described in your premarket notification:

Transducer Model Number

3C5A	7L5
C5-2	L12-4
V10-4	L7-3
V10-4B	L11-4
6C2	L14-6
7L4A	2P2

4CD4	P12-4
P4-2	7LT4
P7-3	DE10-3

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 Paul Hardy at (301) 796-6542.

Sincerely yours,

for: Donald 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)

Indications for Use

510(k) Number (if known):

Device Name: DC-7 Diagnostic Ultrasound System

Indications For Use:

The DC-7 Diagnostic Ultrasound System is applicable for adults, pregnant women, pediatric patients and neonates. It is intended for use in abdominal, cardiac, small organ (breast, testes, thyroid, etc.), peripheral vascular, fetal, transrectal, transvaginal, pediatric, neonatal cephalic, musculoskeletal(conventional and superficial), intraoperative and transcranial exams.

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)

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

510K K101041

Diagnostic Ultrasound Indications for Use Form

System X Transducer

Model: DC-7

510(k) Number(s)

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal	P	P	P		P	P	P	Note1,2, 3, 4,7,8
Abdominal	P	P	P	P	P	P	P	Note1,2, 3, 4,5,7,8
Intraoperative (specify)*	N	N	N		N	N	N	Note 1,2, 4,7,8
Intraoperative (Neuro)								
Laparoscopic								
Pediatric	P	P	P	P	P	P	P	Note 1, 2, 4,5,7,8
Small organ(specify)**	P	P	P		P	P	P	Note1, 2, 4,7,8
Neonatal Cephalic	P	P	P	P	P	P	P	Note1, 2, 4,5,7,8
Adult Cephalic	P	P	P	P	P	P	P	Note1, 2, 4,5,7,8
Trans-rectal	P	P	P		P	P	P	Note 1,2,3,4,7,8
Trans-vaginal	P	P	P		P	P	P	Note 1,2,3,4,7,8
Trans-urethral								
Trans-esoph.(non-Card.)								
Musculo-skeletal Conventional	P	P	P		P	P	P	Note 1,2,4,7,8
Musculo-skeletal Superficial	P	P	P		P	P	P	Note 1,2,4,7,8
Intravascular								
Cardiac Adult	P	P	P	P	P	P	P	Note 1,2,5,7,8
Cardiac Pediatric	P	P	P	P	P	P	P	Note 1,2,5,7,8
Intravascular (Cardiac)								
Trans-esoph.(Cardiac)								
Intra-Cardiac								
Peripheral Vascular	P	P	P		P	P	P	Note 1,2,4,7,8
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, PW +Color+ B, Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular etc.

**Small organ-breast, thyroid, testes, etc.

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

Note 2: Smart3D

Note 3:4D(Real-time 3D)

Note 4: iScape

Note5: TDI

Note6: Contrast Imaging

Note7: Color M

Note8: 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 K101041

Diagnostic Ultrasound Indications for Use Form

System ____ Transducer X

Model: 3C5A

510(k) Number(s) K093691

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal	P	P	P		P	P	P	Note 1, 2, 4,7,8
Abdominal	P	P	P		P	P	P	Note 1, 2, 4,7,8
Intraoperative (specify)*								
Intraoperative (Neuro)								
Laparoscopic								
Pediatric	P	P	P		P	P	P	Note 1, 2, 4,7,8
Small organ(specify)**								
Neonatal Cephalic								
Adult Cephalic								
Trans-rectal								
Trans-vaginal								
Trans-urethral								
Trans-esoph.(non-Card.)								
Musculo-skeletal Conventional	P	P	P		P	P	P	Note 1, 2, 4,7,8
Musculo-skeletal Superficial								
Intravascular								
Cardiac Adult								
Cardiac Pediatric								
Intravascular (Cardiac)								
Trans-esoph.(Cardiac)								
Intra-Cardiac								
Peripheral Vascular	P	P	P		P	P	P	Note 1, 2, 4,7,8
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, PW +Color+ B, Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular etc.

**Small organ-breast, thyroid, testes, etc.

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

Note 2: Smart3D

Note 3:4D(Real-time 3D)

Note 4: iScape

Note5: TDI

Note6: Contrast Imaging

Note7: Color M

Note8: Biopsy Guidance

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Concurrence of CDRH, Office of Device Evaluation(ODE)

Prescription USE (Per 21 CFR 801.109)

Robert Becker

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

510K K101041

Diagnostic Ultrasound Indications for Use Form

System ____ Transducer X

Model: C5-2

510(k) Number(s) K092691

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal	P	P	P		P	P	P	Note 1, 2, 4,7,8
Abdominal	P	P	P		P	P	P	Note 1, 2, 4,7,8
Intraoperative (specify)*								
Intraoperative (Neuro)								
Laparoscopic								
Pediatric	P	P	P		P	P	P	Note 1, 2, 4,7,8
Small organ(specify)**								
Neonatal Cephalic								
Adult Cephalic								
Trans-rectal								
Trans-vaginal								
Trans-urethral								
Trans-esoph.(non-Card.)								
Musculo-skeletal Conventional	P	P	P		P	P	P	Note 1, 2, 4,7,8
Musculo-skeletal Superficial								
Intravascular								
Cardiac Adult								
Cardiac Pediatric								
Intravascular (Cardiac)								
Trans-esoph.(Cardiac)								
Intra-Cardiac								
Peripheral Vascular	P	P	P		P	P	P	Note 1, 2, 4,7,8
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, PW +Color+ B, Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular etc.

**Small organ-breast, thyroid, testes, etc.

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

Note 2: Smart3D

Note 3:4D(Real-time 3D)

Note 4: iScape

Note5: TDI

Note6: Contrast Imaging

Note7: Color M

Note8: Biopsy Guidance

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Concurrence of CDRH, Office of Device Evaluation(ODE)

Prescription USE (Per 21 CFR 801.109)

Robert Beckey

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

510K K101041

Diagnostic Ultrasound Indications for Use Form

System ____ Transducer X

Model: V10-4

510(k) Number(s) K092691

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal	P	P	P		P	P	P	Note 1, 2, 4,7,8
Abdominal								
Intraoperative (specify)*								
Intraoperative (Neuro)								
Laparoscopic								
Pediatric								
Small organ(specify)**								
Neonatal Cephalic								
Adult Cephalic								
Trans-rectal	P	P	P		P	P	P	Note 1, 2, 4,7,8
Trans-vaginal	P	P	P		P	P	P	Note 1, 2, 4,7,8
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 Vascular								
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, PW +Color+ B, Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular etc.

**Small organ-breast, thyroid, testes, etc.

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

Note 2: Smart3D

Note 3:4D(Real-time 3D)

Note 4: iScape

Note5: TDI

Note6: Contrast Imaging

Note7: Color M

Note8: 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 K101041

Diagnostic Ultrasound Indications for Use Form

System ____ Transducer X

Model: V10-4B

510(k) Number(s) K092691

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal	P	P	P		P	P	P	Note 1, 2, 4,7,8
Abdominal								
Intraoperative (specify)*								
Intraoperative (Neuro)								
Laparoscopic								
Pediatric								
Small organ(specify)**								
Neonatal Cephalic								
Adult Cephalic								
Trans-rectal	P	P	P		P	P	P	Note 1, 2, 4,7,8
Trans-vaginal	P	P	P		P	P	P	Note 1, 2, 4,7,8
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 Vascular								
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, PW +Color+ B, Power + PW +B.

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Note5: TDI

Note6: Contrast Imaging

Note7: Color M

Note8: 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 K101041

Diagnostic Ultrasound Indications for Use Form

System _____ Transducer X

Model: 6C2

510(k) Number(s) K092691

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal								
Abdominal	P	P	P		P	P	P	Note 1, 2, 4,7,8
Intraoperative (specify)*								
Intraoperative (Neuro)								
Laparoscopic								
Pediatric	P	P	P		P	P	P	Note 1, 2, 4,7,8
Small organ(specify)**								
Neonatal Cephalic	P	P	P		P	P	P	Note 1, 2, 4,7,8
Adult Cephalic	P	P	P		P	P	P	Note 1, 2, 4,7,8
Trans-rectal								
Trans-vaginal								
Trans-urethral								
Trans-esoph.(non-Card.)								
Musculo-skeletal Conventional	P	P	P		P	P	P	Note 1, 2, 4,7,8
Musculo-skeletal Superficial	P	P	P		P	P	P	Note 1, 2, 4,7,8
Intravascular								
Cardiac Adult								
Cardiac Pediatric								
Intravascular (Cardiac)								
Trans-esoph.(Cardiac)								
Intra-Cardiac								
Peripheral Vascular	P	P	P		P	P	P	Note 1; 2, 4,7,8
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, PW +Color+ B, Power + PW +B.

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

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Note 3:4D(Real-time 3D)

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Note5: TDI

Note6: Contrast Imaging

Note7: Color M

Note8: Biopsy Guidance

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Concurrence of CDRH, Office of Device Evaluation(ODE)

Prescription USE (Per 21 CFR 801.109)

Robert Becker

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

510K K101041

Diagnostic Ultrasound Indications for Use Form

System _____ Transducer ×

Model: 7L4A

510(k) Number(s) K092691

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal								
Abdominal	P	P	P		P	P	P	Note 1,2, 4,7,8
Intraoperative (specify)*								
Intraoperative (Neuro)								
Laparoscopic								
Pediatric	P	P	P		P	P	P	Note 1,2, 4,7,8
Small organ(specify)**	P	P	P		P	P	P	Note 1,2, 4,7,8
Neonatal Cephalic	P	P	P		P	P	P	Note 1,2, 4,7,8
Adult Cephalic								
Trans-rectal								
Trans-vaginal								
Trans-urethral								
Trans-esoph.(non-Card.)								
Musculo-skeletal Conventional	P	P	P		P	P	P	Note 1,2, 4,7,8
Musculo-skeletal Superficial	P	P	P		P	P	P	Note 1,2, 4,7,8
Intravascular								
Cardiac Adult								
Cardiac Pediatric								
Intravascular (Cardiac)								
Trans-esoph.(Cardiac)								
Intra-Cardiac								
Peripheral Vascular	P	P	P		P	P	P	Note 1,2, 4,7,8
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, PW +Color+ B, Power + PW +B.

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Note 2: Smart3D

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Note 4: iScape

Note5: TDI

Note6: Contrast Imaging

Note7: Color M

Note8: 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 K101041

Diagnostic Ultrasound Indications for Use Form

System _____ Transducer X

Model: 7L5

510(k) Number(s) K092601

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal								
Abdominal	P	P	P		P	P	P	Note 1,2, 4,7,8
Intraoperative (specify)*								
Intraoperative (Neuro)								
Laparoscopic								
Pediatric	P	P	P		P	P	P	Note 1,2, 4,7,8
Small organ(specify)**	P	P	P		P	P	P	Note 1,2, 4,7,8
Neonatal Cephalic	P	P	P		P	P	P	Note 1,2, 4,7,8
Adult Cephalic								
Trans-rectal								
Trans-vaginal								
Trans-urethral								
Trans-esoph.(non-Card.)								
Musculo-skeletal Conventional	P	P	P		P	P	P	Note 1,2, 4,7,8
Musculo-skeletal Superficial	P	P	P		P	P	P	Note 1,2, 4,7,8
Intravascular								
Cardiac Adult								
Cardiac Pediatric								
Intravascular (Cardiac)								
Trans-esoph.(Cardiac)								
Intra-Cardiac								
Peripheral Vascular	P	P	P		P	P	P	Note 1,2, 4,7,8
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, PW +Color+ B, Power + PW +B.

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

Note 2: Smart3D

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Note 4: iScape

Note5: TDI

Note6: Contrast Imaging

Note7: Color M

Note8: Biopsy Guidance

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Concurrence of CDRH, Office of Device Evaluation(ODE)

Prescription USE (Per 21 CFR 801.109)

Robert T Bodkey

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

510K K101041

Diagnostic Ultrasound Indications for Use Form

System _____ Transducer X

Model: L12-4

510(k) Number(s) K092691

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal								
Abdominal	P	P	P		P	P	P	Note 1,2, 4,7,8
Intraoperative (specify)*								
Intraoperative (Neuro)								
Laparoscopic								
Pediatric	P	P	P		P	P	P	Note 1,2, 4,7,8
Small organ(specify)**	P	P	P		P	P	P	Note 1,2, 4,7,8
Neonatal Cephalic	P	P	P		P	P	P	Note 1,2, 4,7,8
Adult Cephalic								
Trans-rectal								
Trans-vaginal								
Trans-urethral								
Trans-esoph.(non-Card.)								
Musculo-skeletal Conventional	P	P	P		P	P	P	Note 1,2, 4,7,8
Musculo-skeletal Superficial	P	P	P		P	P	P	Note 1,2, 4,7,8
Intravascular								
Cardiac Adult								
Cardiac Pediatric								
Intravascular (Cardiac)								
Trans-esoph.(Cardiac)								
Intra-Cardiac								
Peripheral Vascular	P	P	P		P	P	P	Note 1,2, 4,7,8
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, PW +Color+ B, Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular etc.

**Small organ-breast, thyroid, testes, etc.

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

Note 2: Smart3D

Note 3: 4D(Real-time 3D)

Note 4: iScape

Note5: TDI

Note6: Contrast Imaging

Note7: Color M

Note8: 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 K101641

Diagnostic Ultrasound Indications for Use Form

System _____ Transducer X

Model: L7-3

510(k) Number(s) K102641

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal								
Abdominal	P	P	P		P	P	P	Note 1,2, 4,7,8
Intraoperative (specify)*								
Intraoperative (Neuro)								
Laparoscopic								
Pediatric	P	P	P		P	P	P	Note 1,2, 4,7,8
Small organ(specify)**	P	P	P		P	P	P	Note 1,2, 4,7,8
Neonatal Cephalic	P	P	P		P	P	P	Note 1,2, 4,7,8
Adult Cephalic								
Trans-rectal								
Trans-vaginal								
Trans-urethral								
Trans-esoph.(non-Card.)								
Musculo-skeletal Conventional	P	P	P		P	P	P	Note 1,2, 4,7,8
Musculo-skeletal Superficial	P	P	P		P	P	P	Note 1,2, 4,7,8
Intravascular								
Cardiac Adult								
Cardiac Pediatric								
Intravascular (Cardiac)								
Trans-esoph.(Cardiac)								
Intra-Cardiac								
Peripheral Vascular	P	P	P		P	P	P	Note 1,2, 4,7,8
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, PW +Color+ B, Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular etc.

**Small organ-breast, thyroid, testes, etc.

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

Note 2: Smart3D

Note 3: 4D(Real-time 3D)

Note 4: iScape

Note5 : TDI

Note6 : Contrast Imaging

Note7 : Color M

Note8 : 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 K101041

Diagnostic Ultrasound Indications for Use Form

System _____ Transducer ×

Model: L11-4

510(k) Number(s) K062601

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal								
Abdominal	P	P	P		P	P	P	Note 1,2, 4,7,8
Intraoperative (specify)*								
Intraoperative (Neuro)								
Laparoscopic								
Pediatric	P	P	P		P	P	P	Note 1,2, 4,7,8
Small organ(specify)**	P	P	P		P	P	P	Note 1,2, 4,7,8
Neonatal Cephalic	P	P	P		P	P	P	Note 1,2, 4,7,8
Adult Cephalic								
Trans-rectal								
Trans-vaginal								
Trans-urethral								
Trans-esoph.(non-Card.)								
Musculo-skeletal Conventional	P	P	P		P	P	P	Note 1,2, 4,7,8
Musculo-skeletal Superficial	P	P	P		P	P	P	Note 1,2, 4,7,8
Intravascular								
Cardiac Adult								
Cardiac Pediatric								
Intravascular (Cardiac)								
Trans-esoph.(Cardiac)								
Intra-Cardiac								
Peripheral Vascular	P	P	P		P	P	P	Note 1,2, 4,7,8
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, PW +Color+ B, Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular etc.

**Small organ-breast, thyroid, testes, etc.

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

Note 2: Smart3D

Note 3: 4D(Real-time 3D)

Note 4: iScape

Note5: TDI

Note6: Contrast Imaging

Note7: Color M

Note8: 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 K101041

Diagnostic Ultrasound Indications for Use Form

System _____ Transducer X

Model: L14-6

510(k) Number(s) K101041

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal								
Abdominal	P	P	P		P	P	P	Note 1,2, 4,7,8
Intraoperative (specify)*								
Intraoperative (Neuro)								
Laparoscopic								
Pediatric	P	P	P		P	P	P	Note 1,2, 4,7,8
Small organ(specify)**	P	P	P		P	P	P	Note 1,2, 4,7,8
Neonatal Cephalic	P	P	P		P	P	P	Note 1,2, 4,7,8
Adult Cephalic								
Trans-rectal								
Trans-vaginal								
Trans-urethral								
Trans-esoph.(non-Card.)								
Musculo-skeletal Conventional	P	P	P		P	P	P	Note 1,2, 4,7,8
Musculo-skeletal Superficial	P	P	P		P	P	P	Note 1,2, 4,7,8
Intravascular								
Cardiac Adult								
Cardiac Pediatric								
Intravascular (Cardiac)								
Trans-esoph.(Cardiac)								
Intra-Cardiac								
Peripheral Vascular	P	P	P		P	P	P	Note 1,2, 4,7,8
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, PW +Color+ B, Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular etc.

**Small organ-breast, thyroid, testes, etc.

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

Note 2: Smart3D

Note 3: 4D(Real-time 3D)

Note 4: iScape

Note5: TDI

Note6: Contrast Imaging

Note7: Color M

Note8: Biopsy Guidance

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Concurrence of CDRH, Office of Device Evaluation(ODE)

Prescription USE (Per 21 CFR 801.109)

Robert Beakey

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

510K K101041

Diagnostic Ultrasound Indications for Use Form

System ____ Transducer X

Model: 2P2

510(k) Number(s) K092691

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal								
Abdominal	P	P	P	P	P	P	P	Note 1, 2,5,7,8
Intraoperative (specify)*								
Intraoperative (Neuro)								
Laparoscopic								
Pediatric	P	P	P	P	P	P	P	Note 1, 2,5,7,8
Small organ(specify)**								
Neonatal Cephalic	P	P	P	P	P	P	P	Note 1, 2,5,7,8
Adult Cephalic	P	P	P	P	P	P	P	Note 1, 2,5,7,8
Trans-rectal								
Trans-vaginal								
Trans-urethral								
Trans-esoph.(non-Card.)								
Musculo-skeletal Conventional								
Musculo-skeletal Superficial								
Intravascular								
Cardiac Adult	P	P	P	P	P	P	P	Note 1, 2,5,7,8
Cardiac Pediatric	P	P	P	P	P	P	P	Note 1, 2,5,7,8
Intravascular (Cardiac)								
Trans-esoph.(Cardiac)								
Intra-Cardiac								
Peripheral Vascular								
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, PW +Color+ B, Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular etc.

**Small organ-breast, thyroid, testes, etc.

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

Note 2: Smart3D

Note 3: 4D(Real-time 3D)

Note 4: iScape

Note5: TDI

Note6: Contrast Imaging

Note7: Color M

Note8: 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 K101041

Diagnostic Ultrasound Indications for Use Form

System ____ Transducer X

Model: 4CD4

510(k) Number(s) K102691

Clinical Application	Mode of Operation							
	B	M	PW D	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal	P	P	P		P	P	P	Note1,2, 3, 4,7
Abdominal	P	P	P		P	P	P	Note1,2, 3, 4,7
Intraoperative (specify)*								
Intraoperative (Neuro)								
Laparoscopic								
Pediatric	P	P	P		P	P	P	Note1,2, 4,7
Small organ(specify)**								
Neonatal Cephalic								
Adult Cephalic								
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 Vascular								
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, PW +Color+ B, Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular etc.

**Small organ-breast, thyroid, testes, etc.

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

Note 2: Smart3D

Note 3: 4D(Real-time 3D)

Note 4: iScape

Note5: TDI

Note6: Contrast Imaging

Note7: Color M

Note8: 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 K101041

Diagnostic Ultrasound Indications for Use Form

System ____ Transducer X

Model: P4-2

510(k) Number(s) ____

Clinical Application	Mode of Operation							
	B	M	PW D	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal								
Abdominal	N	N	N	N	N	N	N	Note 1, 2,5,7,8
Intraoperative (specify)*								
Intraoperative (Neuro)								
Laparoscopic								
Pediatric	N	N	N	N	N	N	N	Note 1, 2,5,7,8
Small organ(specify)**								
Neonatal Cephalic	N	N	N	N	N	N	N	Note 1, 2,5,7,8
Adult Cephalic	N	N	N	N	N	N	N	Note 1, 2,5,7,8
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, 2,5,7,8
Cardiac Pediatric	N	N	N	N	N	N	N	Note 1, 2,5,7,8
Intravascular (Cardiac)								
Trans-esoph.(Cardiac)								
Intra-Cardiac								
Peripheral Vascular								
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, PW +Color+ B, Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular etc.

**Small organ-breast, thyroid, testes, etc.

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

Note 2: Smart3D

Note 3: 4D(Real-time 3D)

Note 4: iScape

Note5: TDI

Note6: Contrast Imaging

Note7: Color M

Note8: Biopsy Guidance

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Office of In Vitro Diagnostic Device Evaluation and Safety

510K K101041

Diagnostic Ultrasound Indications for Use Form

System ____ Transducer X

Model: P7-3

510(k) Number(s) _____

Clinical Application	Mode of Operation							
	B	M	PW D	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal								
Abdominal	N	N	N	N	N	N	N	Note 1, 2,5,7
Intraoperative (specify)*								
Intraoperative (Neuro)								
Laparoscopic								
Pediatric	N	N	N	N	N	N	N	Note 1, 2,5,7
Small organ(specify)**								
Neonatal Cephalic	N	N	N	N	N	N	N	Note 1, 2,5,7
Adult Cephalic	N	N	N	N	N	N	N	Note 1, 2,5,7
Trans-rectal								
Trans-vaginal								
Trans-urethral								
Trans-esoph.(non-Card.)								
Musculo-skeletal Conventional	N	N	N		N	N	N	Note 1, 2,7
Musculo-skeletal Superficial								
Intravascular								
Cardiac Adult	N	N	N	N	N	N	N	Note 1, 2,5,7
Cardiac Pediatric	N	N	N	N	N	N	N	Note 1, 2,5,7
Intravascular (Cardiac)								
Trans-esoph.(Cardiac)								
Intra-Cardiac								
Peripheral Vascular								
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, PW +Color+ B, Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular etc.

**Small organ-breast, thyroid, testes, etc.

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

Note 2: Smart3D

Note 3:4D(Real-time 3D)

Note 4: iScape

Note5: TDI

Note6: Contrast Imaging

Note7: Color M

Note8: 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 K101041

Diagnostic Ultrasound Indications for Use Form

System ____ Transducer X

Model: P12-4

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, 2,5,7
Intraoperative (specify)*								
Intraoperative (Neuro)								
Laparoscopic								
Pediatric	N	N	N	N	N	N	N	Note 1, 2,5,7
Small organ(specify)**								
Neonatal Cephalic	N	N	N	N	N	N	N	Note 1, 2,5,7
Adult Cephalic	N	N	N	N	N	N	N	Note 1, 2,5,7
Trans-rectal								
Trans-vaginal								
Trans-urethral								
Trans-esoph.(non-Card.)								
Musculo-skeletal Conventional	N	N	N		N	N	N	Note 1, 2,7
Musculo-skeletal Superficial								
Intravascular								
Cardiac Adult	N	N	N	N	N	N	N	Note 1, 2,5,7
Cardiac Pediatric	N	N	N	N	N	N	N	Note 1, 2,5,7
Intravascular (Cardiac)								
Trans-esoph.(Cardiac)								
Intra-Cardiac								
Peripheral Vascular								
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, PW +Color+ B, Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular etc.

**Small organ-breast, thyroid, testes, etc.

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

Note 2: Smart3D

Note 3:4D(Real-time 3D)

Note 4: iScape

Note5: TDI

Note6: Contrast Imaging

Note7: Color M

Note8: Biopsy Guidance

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Concurrence of CDRH, Office of Device Evaluation(ODE)

Prescription USE (Per 21 CFR 801.109)

Robert A Becker

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

510K K101041

Diagnostic Ultrasound Indications for Use Form

System _____ Transducer X

Model: 7LT4

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, 4,7,8
Intraoperative (specify)*	N	N	N		N	N	N	Note 1,2, 4,7,8
Intraoperative (Neuro)								
Laparoscopic								
Pediatric	N	N	N		N	N	N	Note 1,2, 4,7,8
Small organ(specify)**	N	N	N		N	N	N	Note 1,2, 4,7,8
Neonatal Cephalic	N	N	N		N	N	N	Note 1,2, 4,7,8
Adult Cephalic								
Trans-rectal								
Trans-vaginal								
Trans-urethral								
Trans-esoph.(non-Card.)								
Musculo-skeletal Conventional	N	N	N		N	N	N	Note 1,2, 4,7,8
Musculo-skeletal Superficial	N	N	N		N	N	N	Note 1,2, 4,7,8
Intravascular								
Cardiac Adult								
Cardiac Pediatric								
Intravascular (Cardiac)								
Trans-esoph.(Cardiac)								
Intra-Cardiac								
Peripheral Vascular	N	N	N		N	N	N	Note 1,2, 4,7,8
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, PW +Color+ B, Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular etc.

**Small organ-breast, thyroid, testes, etc.

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

Note 2: Smart3D

Note 3:4D(Real-time 3D)

Note 4: iScape

Note5: TDI

Note6: Contrast Imaging

Note7: Color M

Note8: Biopsy Guidance

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Office of In Vitro Diagnostic Device Evaluation and Safety

510K K101041

Diagnostic Ultrasound Indications for Use Form

System ____ Transducer X

Model: DE10-3

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, 2,3, 4,7
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, 3,4,7
Trans-vaginal	N	N	N		N	N	N	Note 1, 2, 3,4,7
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 Vascular								
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, PW +Color+ B, Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular etc.

**Small organ-breast, thyroid, testes, etc.

**Small organ-breast, thyroid, testes, etc.

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

Note 2: Smart3D

Note 3:4D(Real-time 3D)

Note 4: iScape

Note5: TDI

Note6: Contrast Imaging

Note7: Color M

Note8: Biopsy Guidance

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