K132779

NOV 19 2013

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92(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 5658
Fax: +86 755 2658 2680

Contact Person:
Wu Zicui
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: July 19, 2013

2. Device Name: DC-N2/DC-N2S Diagnostic Ultrasound System

Classification
Regulatory Class: II
Review Category: Tier II
21 CFR 892.1550 Ultrasonic Pulsed Doppler Imaging System (IYN)
21 CFR 892.1560 Ultrasonic Pulsed Echo Imaging System (IYO)
21 CFR 892.1570 Diagnostic Ultrasound Transducer (ITX)

3. Device Description:

DC-N2/DC-N2S is asoftware controlled, ultrasonic diagnostic system. Its function is to acquire and display ultrasound data in B, M, PW, Color, Power , iScape, Smart 3D or the combined mode (i.e. B/M-Mode, B/PW-mode, B/PW/Color).This system is a Track 3 device that employs an array of probes that include linear array and convex array with a frequency range of approximately 3.5 MHz to 10.0 MHz.

4. Intended Use:

The DC-N2/DC-N2S Diagnostic Ultrasound System is applicable for adults, pregnant women, pediatric and neonates. It is intended for use in fetal, abdominal, pediatric, small organ (breast, thyroid and testes), neonatal cephalic, adult cephalic, trans-rectal, trans-vaginal, musculo-skeletal (conventional, superficial), cardiac (adult and pediatric), peripheral vascular and urology exams.

5. Comparison with Predicate Devices:

DC-N2/DC-N2S Diagnostic Ultrasound System is comparable with and substantially equivalent to these predicate devices:

Predicate Device	Manufacturer	Model	510(k) Control Number
1	Mindray	Z5	K130695
2	Mindray	DC-N3	K123503
3	Mindray	Logiq e	K113690

DC-N2/DC-N2S has the same technological characteristics, are comparable in key safety and effectiveness features, and have the same intended uses and basic operating modes as the predicate devices. All systems transmit ultrasonic energy into patients, perform post processing of received echoes to generate onscreen display of anatomic structures and fluid flow within the body. All systems allow for specialized measurements of structures and flow, and calculations.

6. Non-clinical Tests:

DC-N2/DC-N2S 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 designed to conform with applicable medical safety standards. This device has been tested and evaluated under the following standards:

- UD 2 Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment.
- UD 3 Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
- AAMI / ANSI ES60601-1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
- IEC 60601-1-2 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests (Edition 3)
- IEC 60601-2-37 Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and

monitoring equipment

- ISO14971 Medical devices - Application of risk management to medical devices
- ISO 10993-1 Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
- IEC 62366 Medical devices - Application of usability engineering to medical devices
- IEC 62304 Medical device software - Software life cycle processes

These non-clinical tests relied on in this premarket notification submission can support the determination of substantial equivalence of the subject device.

7. Clinical Studies

Not applicable. The subject of this submission, DC-N2/DC-N2S Diagnostic Ultrasound System, does not require clinical studies to support substantial equivalence.

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 DC-N2/DC-N2S 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
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 19, 2013

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K132779
Trade/Device Name: DC-N2/DC-N2S Diagnostic Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX
Dated: November 4, 2013
Received: November 5, 2013

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

This determination of substantial equivalence applies to the following transducers intended for use with the DC-N2/DC-N2S Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

35C50EA	65EC10EA
65EC10ED	75L38EA
65C15EA	35C20EA
10L24EA	65EB10EA

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K132779

Device Name: The DC-N2/DC-N2S Diagnostic Ultrasound System

Indications for Use:

The DC-N2/DC-N2S Diagnostic Ultrasound System is applicable for adults, pregnant women, pediatric and neonates. It is intended for use in fetal, abdominal, pediatric, small organ(breast, thyroid, testes), neonatal cephalic, adult cephalic, trans-rectal, trans-vaginal, musculo-skeletal(conventional, superficial), cardiac(adult, pediatric), peripheral vascular and urology exams.

Prescription Use__X__ AND/OR Over – The – Counter Use___
(21 CFR Part 801 Subpart D) (21 CFR Part 807 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic and Radiological Health (OIR)

(Division Sign-Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health

510(k) K132779

Diagnostic Ultrasound Indications for Use Form

System × Transducer _____

Model: DC-N2/DC-N2S

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	Note1,2,3,4
Abdominal	N	N	N		N	N	N	Note1,2,3,4
Intraoperative (specify)*								
Intraoperative (Neuro)								
Laparoscopic								
Pediatric	N	N	N		N	N	N	Note1,2,3,4
Small organ(specify)**	N	N	N		N	N	N	Note1,2,3,4
Neonatal Cephalic	N	N	N		N	N	N	Note1,2,3,4
Adult Cephalic	N	N	N		N	N	N	Note1,2,3,4
Trans-rectal	N	N	N		N	N	N	Note1,2,3,4
Trans-vaginal	N	N	N		N	N	N	Note1,2,3,4
Trans-urethral								
Trans-esoph.(non-Card.)								
Musculo-skeletal Conventional	N	N	N		N	N	N	Note1,2,3,4
Musculo-skeletal Superficial	N	N	N		N	N	N	Note1,2,3,4
Intravascular								
Cardiac Adult	N	N	N		N	N	N	Note1,2,3,4
Cardiac Pediatric	N	N	N		N	N	N	Note1,2,3,4
Intravascular (Cardiac)								
Trans-esoph.(Cardiac)								
Intra-Cardiac								
Peripheral vessel	N	N	N		N	N	N	Note1,2,3,4
Other (specify)***	N	N	N		N	N	N	Note1,2,3,4

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: Smart3D

Note 3: iScape

Note 4: Biopsy Guidance

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

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription USE (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

System _____ Transducer ×

Model: 35C50EA

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
Abdominal	P	P	P		P	P	P	Note1.2.3.4
Intraoperative (specify)*								
Intraoperative (Neuro)								
Laparoscopic								
Pediatric	P	P	P		P	P	P	Note1.2.3.4
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	Note1.2.3.4
Musculo-skeletal Superficial								
Intravascular								
Cardiac Adult								
Cardiac Pediatric								
Intravascular (Cardiac)								
Trans-esoph.(Cardiac)								
Intra-Cardiac								
Peripheral vessel	P	P	P		P	P	P	Note1.2.3.4
Other (specify)***								

N=new indication; P=previously cleared by FDA(K130695); 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: Smart3D

Note 3: iScape

Note 4: Biopsy Guidance

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription USE (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

System _____ Transducer X

Model: 65EC10EA

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
Abdominal								
Intraoperative (specify)*								
Intraoperative (Neuro)								
Laparoscopic								
Pediatric								
Small organ(specify)**								
Neonatal Cephalic								
Adult Cephalic								
Trans-rectal	P	P	P		P	P	P	Note1,2,3,4
Trans-vaginal	P	P	P		P	P	P	Note1,2,3,4
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)***	P	P	P		P	P	P	Note1,2,3,4

N=new indication; P=previously cleared by FDA(K130695); 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: Smart3D

Note 3: iScape

Note 4: Biopsy Guidance

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription USE (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

System _____ Transducer ×

Model: 65EC10ED

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	Note1,2,3,4
Abdominal								
Intraoperative (specify)*								
Intraoperative (Neuro)								
Laparoscopic								
Pediatric								
Small organ(specify)**								
Neonatal Cephalic								
Adult Cephalic								
Trans-rectal	N	N	N		N	N	N	Note1,2,3,4
Trans-vaginal	N	N	N		N	N	N	Note1,2,3,4
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	Note1,2,3,4

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: Smart3D

Note 3: iScape

Note 4: Biopsy Guidance

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription USE (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

System _____ Transducer ×

Model: 75L38EA

510(k) Number(s) _____

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	Note1,2,3,4
Intraoperative (specify)*								
Intraoperative (Neuro)								
Laparoscopic								
Pediatric	P	P	P		P	P	P	Note1,2,3,4
Small organ(specify)**	P	P	P		P	P	P	Note1,2,3,4
Neonatal Cephalic	P	P	P		P	P	P	Note1,2,3,4
Adult Cephalic								
Trans-rectal								
Trans-vaginal								
Trans-urethral								
Trans-esoph.(non-Card.)								
Musculo-skeletal Conventional	P	P	P		P	P	P	Note1,2,3,4
Musculo-skeletal Superficial	P	P	P		P	P	P	Note1,2,3,4
Intravascular								
Cardiac Adult								
Cardiac Pediatric								
Intravascular (Cardiac)								
Trans-esoph.(Cardiac)								
Intra-Cardiac								
Peripheral vessel	P	P	P		P	P	P	Note1,2,3,4
Other (specify)***								

N=new indication; P=previously cleared by FDA(K130695); 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: Smart3D

Note 3: iScape

Note 4: Biopsy Guidance

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription USE (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

System _____ Transducer ×

Model: 65C15EA

510(k) Number(s) _____

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	Note1.2.3.4
Intraoperative (specify)*								
Intraoperative (Neuro)								
Laparoscopic								
Pediatric	P	P	P		P	P	P	Note1.2.3.4
Small organ(specify)**								
Neonatal Cephalic	P	P	P		P	P	P	Note1.2.3.4
Adult Cephalic	P	P	P		P	P	P	Note1.2.3.4
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(K130695); 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: Smart3D

Note 3: iScape

Note 4: Biopsy Guidance

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription USE (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

System ____ Transducer ×

Model: 35C20EA

510(k) Number(s) ____

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	Note1.2.3.4
Intraoperative (specify)*								
Intraoperative (Neuro)								
Laparoscopic								
Pediatric	P	P	P		P	P	P	Note1.2.3.4
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	P	P	P		P	P	P	Note1.2.3.4
Cardiac Pediatric	P	P	P		P	P	P	Note1.2.3.4
Intravascular (Cardiac)								
Trans-esoph.(Cardiac)								
Intra-Cardiac								
Peripheral vessel								
Other (specify)***								

N=new indication; P=previously cleared by FDA(K130695); 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: Smart3D

Note 3: iScape

Note 4: Biopsy Guidance

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription USE (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

System _____ Transducer ×

Model: 10L24EA

510(k) Number(s) _____

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	Note1.2.3.4
Intraoperative (specify)*								
Intraoperative (Neuro)								
Laparoscopic								
Pediatric	P	P	P		P	P	P	Note1.2.3.4
Small organ(specify)**	P	P	P		P	P	P	Note1.2.3.4
Neonatal Cephalic	P	P	P		P	P	P	Note1.2.3.4
Adult Cephalic								
Trans-rectal								
Trans-vaginal								
Trans-urethral								
Trans-esoph.(non-Card.)								
Musculo-skeletal Conventional	P	P	P		P	P	P	Note1.2.3.4
Musculo-skeletal Superficial	P	P	P		P	P	P	Note1.2.3.4
Intravascular								
Cardiac Adult								
Cardiac Pediatric								
Intravascular (Cardiac)								
Trans-esoph.(Cardiac)								
Intra-Cardiac								
Peripheral vessel	P	P	P		P	P	P	Note1.2.3.4
Other (specify)***								

N=new indication; P=previously cleared by FDA(K130695); 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: Smart3D

Note 3: iScape

Note 4: Biopsy Guidance

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription USE (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

System _____ Transducer ×

Model: 65EB10EA

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	Note1,2,3,4
Abdominal								
Intraoperative (specify)*								
Intraoperative (Neuro)								
Laparoscopic								
Pediatric								
Small organ(specify)**								
Neonatal Cephalic								
Adult Cephalic								
Trans-rectal	N	N	N		N	N	N	Note1,2,3,4
Trans-vaginal	N	N	N		N	N	N	Note1,2,3,4
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	Note1,2,3,4

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: Smart3D

Note 3: iScape

Note 4: Biopsy Guidance

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription USE (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health

510(k) _____