December 13, 2017

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
% Mrs. Jean Lei
Engineer of Technical Regulation Department
Mindray Building, Keji 12th Road South
Hi-tech Industrial Park, Nanshan
Shenzhen, Guangdong 518057
P R CHINA

Re: K173369
Trade/Device Name: DC-30/DC-32/DC-28/DC-26/DC-25 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: October 27, 2017
Received: October 27, 2017

Dear Mrs. Lei:

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.

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.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael D. O'Hara For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K173369

Device Name
DC-30/DC-32/DC-28/DC-26/DC-25 Diagnostic Ultrasound System

Indications for Use *(Describe)*
Diagnostic Ultrasound System is applicable for adults, pregnant women, pediatric patients and neonates. It is intended for use in fetal, abdominal, 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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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System: DC-30/DC-32/DC-28/DC-26/DC-25 Diagnostic Ultrasound System

Transducer: /

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

Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	N	N	N		N	N	N	Note 1, 2, 3, 4, 5
	Abdominal	N	N	N		N	N	N	Note 1, 2, 3, 4, 5, 7
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	N	N	N		N	N	N	Note 1, 2, 4, 5
	Small Organ (Specify**)	N	N	N		N	N	N	Note 1, 2, 4, 5, 6
	Neonatal Cephalic	N	N	N		N	N	N	Note 1, 2, 4, 5
	Adult Cephalic	N	N	N		N	N	N	Note 1, 2, 4, 5
	Trans-rectal	N	N	N		N	N	N	Note 1, 2, 4, 5
	Trans-vaginal	N	N	N		N	N	N	Note 1, 2, 4, 5
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	N	N	N		N	N	N	Note 1, 2, 4, 5, 6
	Musculo-skeletal (Superficial)	N	N	N		N	N	N	Note 1, 2, 4, 5, 6
	Intravascular								
Cardiac	Cardiac Adult	N	N	N		N	N	N	Note 1, 2, 4, 5
	Cardiac Pediatric	N	N	N		N	N	N	Note 1, 2, 4, 5
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel	N	N	N		N	N	N	Note 1, 2, 4, 5
	Other (Specify***)	N	N	N		N	N	N	Note 1, 2, 4, 5

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.

***Other use includes Urology.

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

Note 2: Smart3D

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

Note 4: iScape

Note 5: Biopsy Guidance

Note 6: Elastography

Note 7: Contrast imaging (Contrast agent for Liver)

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

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

Prescription USE (Per 21 CFR 801.109)

System: DC-30/DC-32/DC-28/DC-26/DC-25 Diagnostic Ultrasound System

Transducer: 35C50P

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

Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	N	N	N		N	N	N	Note 1, 2, 4, 5
	Abdominal	N	N	N		N	N	N	Note 1, 2, 4, 5, 7
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	N	N	N		N	N	N	Note 1, 2, 4, 5
	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, 4, 5
	Musculo-skeletal (Superficial)								
	Intravascular								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel	N	N	N		N	N	N	Note 1, 2, 4, 5
	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.

***Other use includes Urology.

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

Note 2: Smart3D

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

Note 4: iScape

Note 5: Biopsy Guidance

Note 6: Elastography

Note 7: Contrast imaging (Contrast agent for Liver)

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

Prescription USE (Per 21 CFR 801.109)

System: DC-30/DC-32/DC-28/DC-26/DC-25 Diagnostic Ultrasound System

Transducer: 75L38P

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

Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal	N	N	N		N	N	N	Note 1, 2, 4, 5
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	N	N	N		N	N	N	Note 1, 2, 4, 5
	Small Organ (Specify**)	N	N	N		N	N	N	Note 1, 2, 4, 5, 6
	Neonatal Cephalic	N	N	N		N	N	N	Note 1, 2, 4, 5
	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, 5, 6
	Musculo-skeletal (Superficial)	N	N	N		N	N	N	Note 1, 2, 4, 5, 6
	Intravascular								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel	N	N	N		N	N	N	Note 1, 2, 4, 5
	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.

***Other use includes Urology.

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

Note 2: Smart3D

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

Note 4: iScape

Note 5: Biopsy Guidance

Note 6: Elastography

Note 7: Contrast imaging (Contrast agent for Liver)

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

Prescription USE (Per 21 CFR 801.109)

System: DC-30/DC-32/DC-28/DC-26/DC-25 Diagnostic Ultrasound System

Transducer: 6CV1P

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

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

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.

***Other use includes Urology.

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

Note 2: Smart3D

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

Note 4: iScape

Note 5: Biopsy Guidance

Note 6: Elastography

Note 7: Contrast imaging (Contrast agent for Liver)

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

Prescription USE (Per 21 CFR 801.109)

System: DC-30/DC-32/DC-28/DC-26/DC-25 Diagnostic Ultrasound System

Transducer: 6C2P

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

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

***Other use includes Urology.

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

Note 2: Smart3D

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

Note 4: iScape

Note 5: Biopsy Guidance

Note 6: Elastography

Note 7: Contrast imaging (Contrast agent for Liver)

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

Prescription USE (Per 21 CFR 801.109)

System: DC-30/DC-32/DC-28/DC-26/DC-25 Diagnostic Ultrasound System

Transducer: D6-2P

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

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

*Intraoperative includes abdominal, thoracic, and vascular etc.

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

Note 4: iScape

Note 5: Biopsy Guidance

Note 6: Elastography

Note 7: Contrast imaging (Contrast agent for Liver)

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

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

Prescription USE (Per 21 CFR 801.109)

System: DC-30/DC-32/DC-28/DC-26/DC-25 Diagnostic Ultrasound System

Transducer: 7L4P

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

Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal	N	N	N		N	N	N	Note 1, 2, 4, 5
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	N	N	N		N	N	N	Note 1, 2, 4, 5
	Small Organ (Specify**)	N	N	N		N	N	N	Note 1, 2, 4, 5
	Neonatal Cephalic	N	N	N		N	N	N	Note 1, 2, 4, 5
	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, 5
	Musculo-skeletal (Superficial)	N	N	N		N	N	N	Note 1, 2, 4, 5
	Intravascular								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel	N	N	N		N	N	N	Note 1, 2, 4, 5
	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.

***Other use includes Urology.

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

Note 2: Smart3D

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

Note 4: iScape

Note 5: Biopsy Guidance

Note 6: Elastography

Note 7: Contrast imaging (Contrast agent for Liver)

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

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

Prescription USE (Per 21 CFR 801.109)

System: DC-30/DC-32/DC-28/DC-26/DC-25 Diagnostic Ultrasound System

Transducer: 3C5P

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

Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	N	N	N		N	N	N	Note 1, 2, 4, 5
	Abdominal	N	N	N		N	N	N	Note 1, 2, 4, 5
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	N	N	N		N	N	N	Note 1, 2, 4, 5
	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, 4, 5
	Musculo-skeletal (Superficial)								
	Intravascular								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel	N	N	N		N	N	N	Note 1, 2, 4, 5
	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.

***Other use includes Urology.

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

Note 2: Smart3D

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

Note 4: iScape

Note 5: Biopsy Guidance

Note 6: Elastography

Note 7: Contrast imaging (Contrast agent for Liver)

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

Prescription USE (Per 21 CFR 801.109)

System: DC-30/DC-32/DC-28/DC-26/DC-25 Diagnostic Ultrasound System

Transducer: CB10-4P

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

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

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.

***Other use includes Urology.

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

Note 2: Smart3D

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

Note 4: iScape

Note 5: Biopsy Guidance

Note 6: Elastography

Note 7: Contrast imaging (Contrast agent for Liver)

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

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

Prescription USE (Per 21 CFR 801.109)

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).

1. Submitter:

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Date Prepared: October 24, 2017

2. Device Name: DC-30/DC-32/DC-28/DC-26/DC-25 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-30/DC-32/DC-28/DC-26/DC-25 Diagnostic Ultrasound System is a general purpose, mobile, software controlled, ultrasound diagnostic system. Its function is to acquire and display ultrasound images in B-mode, M-mode, PW-mode, Color-mode, Power/Dirpower mode, THI mode, 3D/4D mode, iScape mode, Biopsy Guidance, Elastography, Contrast imaging (Contrast agent for Liver) 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.

4. Intended Use:

Diagnostic Ultrasound System is applicable for adults, pregnant women, pediatric patients and neonates. It is intended for use in fetal, abdominal, 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:

DC-30/DC-32/DC-28/DC-26/DC-25 Diagnostic Ultrasound System is comparable with and substantially equivalent to these predicate devices:

Type	Manufacturer	Model	510(k) Number
Predicate Device	Mindray	DC-N3	K140030
Reference device	Mindray	DC-8	K170277
Reference device	Mindray	M9	K171034

The DC-30/DC-32/DC-28/DC-26/DC-25 Diagnostic Ultrasound System employs the same technology as the predicate devices. All systems transmit ultrasonic energy into patients, and then 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. The subject device also has the same intended uses and basic operating modes as the predicate devices.

- Subject device DC-30/DC-32/DC-28/DC-26/DC-25 has the same intended uses as the predicated device DC-N3 (K140030).

Items	**Subject Device** DC-30/DC-32/DC-28/DC-26/DC-25	**Predicate device** DC-N3 (K140030)
Intended Use	DC-30/DC-32/DC-28/DC-26/DC-25 Diagnostic Ultrasound System is applicable for adults, pregnant women, pediatric patients and neonates. It is intended for use in fetal, abdominal, pediatric, small organ(breast, thyroid, testes), neonatal cephalic,	The DC-N3 diagnostic ultrasound system is applicable for adults, pregnant women, pediatric patients 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), musculo-skeletal(superficial), cardiac adult, cardiac pediatric, peripheral vessel, and urology exams.	adult cephalic, trans-rectal, trans-vaginal, musculo-skeletal(conventional), musculo-skeletal(superficial), cardiac adult, cardiac pediatric, peripheral vessel and urology exams.

- The patient contact materials of the transducers are tested under ISO 10993-1.
- The acoustic power levels of the DC-30/DC-32/DC-28/DC-26/DC-25 are below the limits of FDA, which are the same as the predicated device DC-N3 (K140030).
- DC-30/DC-32/DC-28/DC-26/DC-25 is designed in compliance with the FDA recognized electrical and physical safety standards, which are the same as the predicated device DC-N3 (K140030).
- Modes and features
  - The DC-30/DC-32/DC-28/DC-26/DC-25 has the same imaging modes as the predicated device including B mode, M mode, Color mode, Power/DirPower mode, PW mode and Free Xros M (Anatomical M mode).
  - The DC-30/DC-32/DC-28/DC-26/DC-25 has the same special features as the predicate device including Static 3D, Smart 3D, 4D, iPage, iScape View, IMT and iScanHelper.
  - The DC-30/DC-32/DC-28/DC-26/DC-25 share the same options as the predicate device except Ultrasound gel warmer and IVF, which are the same as the reference device.
  - Measurements of the subject device are the same as the predicate device except MAD, which is the same as the reference device.
  - Following features of subject device DC-30/DC-32/DC-28/DC-26/DC-25 are the same as the reference devices.

Items	Reference device
Contrast imaging for liver	DC-8(K170277)
Elastography	
Ultrasound gel warmer	
IVF	
MAD measurement	M9(K171034)

- Transducers
  - 35C50P of DC-30/DC-32/DC-28/DC-26/DC-25 has new indication of contrast imaging for liver as compared to predicate device; however, this feature is the same as the feature on the reference device DC-8(K170277).
  - 75L38P of DC-30/DC-32/DC-28/DC-26/DC-25 has new indication of elastography as compared to predicate device; however, this feature is the same as the feature on the reference device DC-8(K170277).

6. Non-clinical Tests:

DC-30/DC-32/DC-28/DC-26/DC-25 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.

Non-clinical tests relied on in this premarket notification submission for a determination of substantial equivalence include testing showing compliance with the following standards:

- AAMI / ANSI ES60601-1:2005/(R)2012 and A1:2012,, c1:2009/(r)2012 and a2:2010/(r)2012 (consolidated text) medical electrical equipment - part 1: general requirements for basic safety and essential performance (iec 60601-1:2005, mod).
- IEC 60601-1-2 Edition 3: 2007-03, medical electrical equipment - part 1-2: general requirements for basic safety and essential performance - collateral standard: electromagnetic compatibility - requirements and tests.
- IEC 60601-2-37 Edition 2.0 2007, medical electrical equipment - part 2-37: particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment.
- AAMI / ANSI / IEC 62304:2006, medical device software - software life cycle processes.
- AAMI / ANSI / IEC 62366:2007/(R)2013:Medical devices - application of usability engineering to medical devices
- IEC 60601-1-6 Edition 3.1 2013-10: medical electrical equipment - part 1-6: general requirements for basic safety and essential performance - collateral standard: usability.
- ISO 14971 Second edition 2007-03-01, medical devices - application of risk management to medical devices.
- NEMA UD 2-2004 (R2009), acoustic output measurement standard for diagnostic ultrasound equipment revision 3.
- AAMI / ANSI / ISO 10993-1:2009/(R)2013, biological evaluation of medical

devices - part 1: evaluation and testing within a risk management process.

- NEMA UD 3 Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment

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-30/DC-32/DC-28/DC-26/DC-25 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-30/DC-32/DC-28/DC-26/DC-25 Diagnostic Ultrasound System is substantially equivalent with respect to safety and effectiveness to devices currently cleared for market.