



Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
% Zhang Wei
Engineer of Technical Regulation
Keji 12th Road South, Hi-tech Industrial Park
Shenzhen, Guangdong 518057
CHINA

March 8, 2019

Re: K190206

Trade/Device Name: DC-90/DC-90S/DC-90Q/DC-95/DC-95S/DC-88/DC-88S/
DC-80A/DC/80A Exp/DC-80A Pro/DC-8X/DC-8Q/DC-81/DC82
Diagnostic Ultrasound System

Regulation Number: 21 CFR 892.1550

Regulation Name: Ultrasonic pulsed doppler imaging system

Regulatory Class: Class II

Product Code: IYN, IYO, ITX, LLZ

Dated: January 25, 2019

Received: February 4, 2019

Dear Zhang Wei:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see <https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 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,

A handwritten signature in black ink, appearing to read 'Thalia Mills', is written over a large, light blue, semi-transparent watermark of the letters 'FDA'.

for
Thalia Mills, Ph.D.
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)

K190206

Device Name

DC-90/DC-90S/DC-90Q/DC-95/DC-95S/DC-88/DC-88S/DC-80A/DC-80A Exp/DC-80A Pro/DC-8X/DC-8Q/DC-81/DC-82
Diagnostic Ultrasound System

Indications for Use (Describe)

DC-90/DC-90S/DC-90Q/DC-95/DC-95S/DC-88/DC-88S/DC-80A/DC-80A Exp/DC-80A Pro/DC-8X/DC-8Q/DC-81/DC-82 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), adult and pediatric cardiac, 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

System:	DC-90/DC-90S/DC-90Q/DC-95/DC-95S/DC-88/DC-88S/DC-80A/DC-80A Exp/DC-80A Pro/DC-8X/DC-8Q/DC-81/DC-82 Diagnostic Ultrasound System								
Transducer:	N/A								
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, 6, 7
	Abdominal	N	N	N	N	N	N	N	Note 1, 2,3, 4,6,7,9,11,12
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	N	N	N	N	N	N	N	Note 1, 2, 4,6,7
	Small Organ (Specify**)	N	N	N		N	N	N	Note 1,2, 4,7,8,11,12
	Neonatal Cephalic	N	N	N	N	N	N	N	Note 1, 2, 4,6,7
	Adult Cephalic	N	N	N	N	N	N	N	Note 1,2,4,6,7
	Trans-rectal	N	N	N		N	N	N	Note 1, 2,3, 4, 6, 7, 8
	Trans-vaginal	N	N	N		N	N	N	Note 1, 2,3, 4, 6, 7, 8
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	N	N	N		N	N	N	Note 1, 2, 4,6,7,8,11,12
	Musculo-skeletal (Superficial)	N	N	N		N	N	N	Note 1, 2, 4,7,8,11,12
	Intravascular								
Cardiac	Cardiac Adult	N	N	N	N	N	N	N	Note 1, 2,4,5,6,7,10
	Cardiac Pediatric	N	N	N	N	N	N	N	Note 1, 2, 4,5,6,7
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel	N	N	N		N	N	N	Note 1, 2, 4,6,7
	Other (Specify***)	N	N	N		N	N	N	Note 1, 2, 4, 6, 7,8
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 3:4D(Real-time 3D)									
Note 4: iScape									
Note 5: TDI									
Note 6: Color M									
Note 7: Biopsy Guidance									
Note 8: Strain Elastography									
Note 9: Contrast imaging (Contrast agent for Liver)									
Note 10: Contrast imaging(contrast agent for LVO)									
Note 11: STE									
Note 12: STQ									
(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-90/DC-90S/DC-90Q/DC-95/DC-95S/DC-88/DC-88S/DC-80A/DC-80A Exp/DC-80A Pro/DC-8X/DC-8Q/DC-81/DC-82 Diagnostic Ultrasound System								
Transducer:	C11-3E								
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, 4,6,7
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	N	N	N		N	N	N	Note 1, 2, 4,6,7
	Small Organ (Specify**)								
	Neonatal Cephalic	N	N	N		N	N	N	Note 1, 2, 4,6,7
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Cardiac	Cardiac Adult							
Cardiac Pediatric		N	N	N		N	N	N	Note 1, 2, 4,6,7
Intravascular (Cardiac)									
Trans-esoph. (Cardiac)									
Intra-cardiac									
Peripheral vessel	Peripheral vessel	N	N	N		N	N	N	Note 1, 2, 4,6,7
	Other (Specify***)								
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Additional comments: Combined modes--B+M、PW+B、Color + B、Power+B、PW+Color+B、Power+PW+B.									
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Transducer:	L12-3E								
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, 4,7
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	N	N	N		N	N	N	Note 1, 2, 4,7
	Small Organ (Specify**)	N	N	N		N	N	N	Note 1,2, 4,7,8,11,12
	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, 4,7,11,12
	Musculo-skeletal (Superficial)	N	N	N		N	N	N	Note 1, 2, 4,7,11,12
	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, 4,7
	Other (Specify***)								
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Additional comments: Combined modes--B+M、PW+B、Color + B、Power+B、PW+Color+B、Power+PW+B.									
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Transducer:	P7-3E								
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	N	Note 1,2,4,6
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	N	N	N	N	N	N	N	Note 1,2,4,6
	Small Organ (Specify**)								
	Neonatal Cephalic	N	N	N	N	N	N	N	Note 1,2,4,6
	Adult Cephalic	N	N	N	N	N	N	N	Note 1,2,4,6
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
Cardiac	Intravascular								
	Cardiac Adult	N	N	N	N	N	N	N	Note 1, 2,4,5,6
	Cardiac Pediatric	N	N	N	N	N	N	N	Note 1, 2,4,5,6
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
Peripheral vessel	Intra-cardiac								
	Peripheral vessel								
	Other (Specify***)								
N=new indication; P=previously cleared by FDA; E=added under Appendix E									
Additional comments: Combined modes--B+M、PW+B、Color + B、Power+B、PW+Color+B、Power+PW+B.									
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Transducer:	L9-3E								
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, 4,7
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	N	N	N		N	N	N	Note 1,2, 4,7
	Small Organ (Specify**)	N	N	N		N	N	N	Note 1,2, 4,7,8,11,12
	Neonatal Cephalic								
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	Musculo-skeletal (Superficial)	N	N	N		N	N	N	Note 1,2, 4,7,11,12
	Intravascular								
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Peripheral vessel	Peripheral vessel	N	N	N		N	N	N	Note 1,2, 4,7
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Additional comments: Combined modes--B+M、PW+B、Color + B、Power+B、PW+Color+B、Power+PW+B.									
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Transducer:	DE11-3E								
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, 3, 4, 6, 7
	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, 3, 4, 6, 7, 8
	Trans-vaginal	N	N	N		N	N	N	Note 1, 3, 4, 6, 7, 8
	Trans-urethral								
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Transducer:	V11-3HE								
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, 6, 7
	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, 6, 7, 8
	Trans-vaginal	N	N	N		N	N	N	Note 1, 2, 4, 6, 7, 8
	Trans-urethral								
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Additional comments: Combined modes--B+M, PW+B, Color + B, Power+B, PW+Color+B, Power+PW+B.									
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Fetal Imaging & Other	Fetal									
	Abdominal	N	N	N	N	N	N	N	Note 1, 2,4, 6,7	
	Intra-operative (Specify*)									
	Intra-operative (Neuro)									
	Laparoscopic									
	Pediatric	N	N	N	N	N	N	N	Note 1, 2,4, 6,7	
	Small Organ (Specify**)									
	Neonatal Cephalic									
	Adult Cephalic	N	N	N	N	N	N	N	Note 1, 2,4, 6,7	
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	Trans-esoph. (non-Card.)									
	Musculo-skeletal (Conventional)									
	Musculo-skeletal (Superficial)									
	Intravascular									
Cardiac	Cardiac Adult	N	N	N	N	N	N	N	Note 1, 2,4,5,6,7,10	
	Cardiac Pediatric	N	N	N	N	N	N	N	Note 1, 2,4,5,6,7	
	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: TDI										
Note 6: Color M										
Note 7: Biopsy Guidance										
Note 8: Elastography										
Note 9: Contrast imaging (Contrast agent for Liver)										
Note 10: Contrast imaging(contrast agent for LVO)										
Note 11: STE										
Note 12: STQ										
(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-90/DC-90S/DC-90Q/DC-95/DC-95S/DC-88/DC-88S/DC-80A/DC-80A Exp/DC-80A Pro/DC-8X/DC-8Q/DC-81/DC-82 Diagnostic Ultrasound System								
Transducer:	SC6-1E								
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, 6,7
	Abdominal	N	N	N		N	N	N	Note 1, 2, 4,6,7,9,11,12
	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)	N	N	N		N	N	N	Note 1, 2, 4,6,7
	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, 4,6,7
	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.									
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Note 1: Tissue Harmonic Imaging.									
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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-90/DC-90S/DC-90Q/DC-95/DC-95S/DC-88/DC-88S/DC-80A/DC-80A Exp/DC-80A Pro/DC-8X/DC-8Q/DC-81/DC-82 Diagnostic Ultrasound System								
Transducer:	SD8-1E								
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, 3, 4, 6,7
	Abdominal	N	N	N		N	N	N	Note 1, 3, 4,6,7
	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.									
**Small organ-breast, thyroid, testes.									
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Note 1: Tissue Harmonic Imaging.									
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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-90/DC-90S/DC-90Q/DC-95/DC-95S/DC-88/DC-88S/DC-80A/DC-80A Exp/DC-80A Pro/DC-8X/DC-8Q/DC-81/DC-82 Diagnostic Ultrasound System								
Transducer:	L14-5WE								
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, 4,7
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	N	N	N		N	N	N	Note 1,2, 4,7
	Small Organ (Specify**)	N	N	N		N	N	N	Note 1,2, 4,7,8,11,12
	Neonatal Cephalic	N	N	N		N	N	N	Note 1,2, 4,7
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	N	N	N		N	N	N	Note 1,2, 4,7,11,12
	Musculo-skeletal (Superficial)	N	N	N		N	N	N	Note 1,2, 4,7,11,12
	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, 4,7
	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.									
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Note 12: STQ									
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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-90/DC-90S/DC-90Q/DC-95/DC-95S/DC-88/DC-88S/DC-80A/DC-80A Exp/DC-80A Pro/DC-8X/DC-8Q/DC-81/DC-82 Diagnostic Ultrasound System										
Transducer:	L20-5E										
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**)	N	N	N		N	N	N	Note 1, 2, 4		
	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, 8		
	Musculo-skeletal (Superficial)	N	N	N		N	N	N	Note 1, 2, 4, 8		
	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		
	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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System:	DC-90/DC-90S/DC-90Q/DC-95/DC-95S/DC-88/DC-88S/DC-80A/DC-80A Exp/DC-80A Pro/DC-8X/DC-8Q/DC-81/DC-82 Diagnostic Ultrasound System								
Transducer:	SC5-1NE								
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, 6,7
	Abdominal	N	N	N		N	N	N	Note 1, 2, 4,6,7
	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)	N	N	N		N	N	N	Note 1, 2, 4,6,7
	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, 4,6,7
	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.									
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Note 12: STQ									
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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)									
Prescription USE (Per 21 CFR 801.109)									

510(K) SUMMARY

K190206

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.

1. Submitter:

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Date Prepared: January 25, 2019

2. Device Name:

DC-90/DC-90S/DC-90Q/DC-95/DC-95S/DC-88/DC-88S/DC-80A/DC-80A

Exp/DC-80A Pro/DC-8X/DC-8Q/DC-81/DC-82 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)

21 CFR 892.2050 Picture Archiving and Communications System(LLZ)

3. Device Description:

DC-90/DC-90S/DC-90Q/DC-95/DC-95S/DC-88/DC-88S/DC-80A/DC-80A

Exp/DC-80A Pro/DC-8X/DC-8Q/DC-81/DC-82 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, CW mode, Color-mode, Color M-mode, Power/Dirpower mode, TDI mode, THI, iScape, Biopsy Guidance, 3D/4D mode, Elastography, Contrast imaging 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:

The DC-80A /DC-80A Exp/DC-80A

DC-90/DC-90S/DC-90Q/DC-95/DC-95S/DC-88/DC-88S/DC-80A/DC-80A

Exp/DC-80A Pro/DC-8X/DC-8Q/DC-81/DC-82 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), adult and pediatric cardiac, peripheral vessel and urology exams.

5. Comparison with Predicate Devices:

DC-90/DC-90S/DC-90Q/DC-95/DC-95S/DC-88/DC-88S/DC-80A/DC-80A

Exp/DC-80A Pro/DC-8X/DC-8Q/DC-81/DC-82 Diagnostic Ultrasound System is comparable with and substantially equivalent to these predicate devices:

Predicate Device	Manufacturer	Model	510(k) Control Number
1. Primary predicate device	Mindray	DC-70	K181637
2. Reference device	Mindray	Resona 7	K171233

DC-90/DC-90S/DC-90Q/DC-95/DC-95S/DC-88/DC-88S/DC-80A/DC-80A

Exp/DC-80A Pro/DC-8X/DC-8Q/DC-81/DC-82 Diagnostic Ultrasound System employs the same technology as the predicate devices. All systems transmit ultrasonic energy into patients, 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-90/DC-90S/DC-90Q/DC-95/DC-95S/DC-88/DC-88S/DC-80A/DC-80A

Exp/DC-80A Pro/DC-8X/DC-8Q/DC-81/DC-82 has the similar intended uses with the predicated device DC-70(K181637) .

■ The materials of probes and Needle-guided brackets of

DC-90/DC-90S/DC-90Q/DC-95/DC-95S/DC-88/DC-88S/DC-80A/DC-80A

Exp/DC-80A Pro/DC-8X/DC-8Q/DC-81/DC-82 are the same to the predicate device DC-70(K181637).

■ The acoustic power levels of

DC-90/DC-90S/DC-90Q/DC-95/DC-95S/DC-88/DC-88S/DC-80A/DC-80A

Exp/DC-80A Pro/DC-8X/DC-8Q/DC-81/DC-82 are below the limits of FDA, which is the same as the predicated device DC-70(K181637).

■ DC-90/DC-90S/DC-90Q/DC-95/DC-95S/DC-88/DC-88S/DC-80A/DC-80A

Exp/DC-80A Pro/DC-8X/DC-8Q/DC-81/DC-82 is designed in compliance with the FDA recognized electrical and physical safety standards, which are the same as the predicated device DC-70(K181637).

The differences between the DC-90 series and the predicate devices:

Predicate Device	Model	Items	Specific differences
1. Primary predicate device	DC-70	Differences of Intended uses	The DC-70 series have more intended uses about Trans-esoph. (Cardiac) and intra-operative (abdominal, thoracic, and vascular). But the DC-90 series don't have.
		Differences of Transducers	The DC-90 series support one new transducer which is SC5-1NE. The other transducers that SC6-1E, C11-3E, L12-3E, L9-3E, V11-3HE, SP5-1E, P7-3E, SD8-1E, L14-5WE, L20-5E, DE11-3E were cleared by

			DC-70.
		Hardware platform improvement	One more transducer port of DC-90 series.
			The battery of DC-90 series can provide power supply when working.
			The DC-90 series have two hard disks (128G SSD+1T HDD) and the DC-70 series only have one hard disk (1T HDD).
			The signal channel between the probe and the main host is 128. The DC-70 series only have 64.
		Differences of Software Functions	The DC-90 series have new Software Functions: STE, STQ, Smart Pelvic and Dehaze;
2. Reference device	Resona 7	New Software Functions	The Software Functions about STE, STQ, Smart Pelvic were cleared in Resona 7 (K171233)

6. Non-clinical Tests:

DC-90/DC-90S/DC-90Q/DC-95/DC-95S/DC-88/DC-88S/DC-80A/DC-80A

Exp/DC-80A Pro/DC-8X/DC-8Q/DC-81/DC-82 Diagnostic Ultrasound System has been evaluated for software, cybersecurity testing, acoustic output, biocompatibility, cleaning and disinfection effectiveness as well as thermal, electrical and mechanical safety, and has been found to conform with applicable medical safety standards.

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 4.0 2014-02, 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 2.1 2015, medical electrical equipment - part 2-37:

particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment.

- IEC 62304 Edition 1.1 2015-06, medical device software - software life cycle processes.
- 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.
- IEC 62366-1 Edition 1.0 2015-02 Medical devices - Part 1: Application of usability engineering to medical devices [Including CORRIGENDUM 1 (2016)]
- 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

7. Clinical Tests:

Not Applicable.

8. 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-90/DC-90S/DC-90Q/DC-95/DC-95S/DC-88/DC-88S/DC-80A/DC-80A

Exp/DC-80A Pro/DC-8X/DC-8Q/DC-81/DC-82 Diagnostic Ultrasound System is substantially equivalent with respect to safety and effectiveness to devices currently cleared for market.