Shenzhen Mindray Bio-Medical Electronics Co., LTD. May 28, 2020
℅ Shi Jufang
Engineer of Technical Regulation
Keji 12th Road South, Hi-tech Industrial Park
Shenzhen, Guangdong 518057
CHINA

Re: K200979
Trade/Device Name: DP-50/DP-50T/DP-50Expert/DP-50S/DP-50Pro Digital Ultrasonic Diagnostic Imaging System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: April 3, 2020
Received: April 13, 2020

Dear Shi Jufang:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
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)*

K200979

Device Name
DP-50/DP-50T/DP-50Expert/DP-50S/DP-50Pro Digital Ultrasonic Diagnostic Imaging System

Indications for Use *(Describe)*

DP-50/DP-50T/DP-50Expert/DP-50S/DP-50Pro Digital Ultrasonic Diagnostic Imaging System is applicable for adults, pregnant women, pediatric patients and neonates. It is intended for use in fetal, abdominal, Intra-operative (abdominal, thoracic, and vascular),pediatric, small organ(breast, thyroid, testes, etc.), neonatal and adult cephalic, trans-rectal, trans-vaginal, musculo-skeletal(conventional, superficial), cardiac(adult, pediatric), peripheral vascular .The system is designed to be used by a trained operator in a clinical setting.

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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Digital Ultrasonic Diagnostic Imaging System Indications For Use Format									
System:	DP-50/DP-50T/DP-50Expert/DP-50S/DP-50Pro Digital Ultrasonic Diagnostic Imaging 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	P	P	N		N	N	P	Note 1,2,6,7
	Abdominal	P	P	N		N	N	P	Note 1,2,3,6,7
	Intra-operative (Specify*)	N	N	N		N	N	N	Note 1,2,3,6
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	N		N	N	P	Note 1,2,3,6
	Small Organ (Specify**)	P	P	N		N	N	P	Note 1,2,3,6
	Neonatal Cephalic	P	P	N		N	N	P	Note 1,2,3,6
	Adult Cephalic	P	P	N		N	N	P	Note 1,2,6
	Trans-rectal	P	P	N		N	N	P	Note 1,2,6
	Trans-vaginal	P	P	N		N	N	P	Note 1,2,6
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	P	P	N		N	N	P	Note 1,2,3,6
	Musculo-skeletal (Superficial)	P	P	N		N	N	P	Note 1,2,3,6
	Intravascular								
Cardiac	Cardiac Adult	N	N	N		N	N	N	Note 1,2,6
	Cardiac Pediatric	P	P	N		N	N	P	Note 1,2,6
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel	P	P	N		N	N	P	Note 1,2,3,6
	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.									
***Other use includes Urology.									
Note 1: Tissue Harmonic Imaging.									
Note 2: Biopsy Guidance									
Note 3: iScape									
Note 4: TDI									
Note 5: Color M									
Note 6: Smart3D									
Note 7:4D(Real-time 3D)									
(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)									

Digital Ultrasonic Diagnostic Imaging System Indications For Use Format									
System:	DP-50/DP-50T/DP-50Expert/DP-50S/DP-50Pro Digital Ultrasonic Diagnostic Imaging System								
Transducer:	35C50EA								
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	P	P	N		N	N	P	Note 1,2,6
	Abdominal	P	P	N		N	N	P	Note 1,2,6
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	N		N	N	P	Note 1,2,6
	Small Organ (Specify**)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	P	P	N		N	N	P	Note 1,2,6
	Musculo-skeletal (Superficial)								
	Intravascular								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel	P	P	N		N	N	P	Note 1,2,6
	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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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)									
Prescription USE (Per 21 CFR 801.109)									

Digital Ultrasonic Diagnostic Imaging System Indications For Use Format									
System:	DP-50/DP-50T/DP-50Expert/DP-50S/DP-50Pro Digital Ultrasonic Diagnostic Imaging System								
Transducer:	65EC10EA								
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	P	P	N		N	N	P	Note 1,2,6
	Abdominal								
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify**)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal	P	P	N		N	N	P	Note 1,2,6
	Trans-vaginal	P	P	N		N	N	P	Note 1,2,6
	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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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)									
Prescription USE (Per 21 CFR 801.109)									

Digital Ultrasonic Diagnostic Imaging System Indications For Use Format									
System:	DP-50/DP-50T/DP-50Expert/DP-50S/DP-50Pro Digital Ultrasonic Diagnostic Imaging System								
Transducer:	75L38EA								
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	P	P	N		N	N	P	Note 1,2,3,6
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	N		N	N	P	Note 1,2,3,6
	Small Organ (Specify**)	P	P	N		N	N	P	Note 1,2,3,6
	Neonatal Cephalic	P	P	N		N	N	P	Note 1,2,3,6
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	P	P	N		N	N	P	Note 1,2,3,6
	Musculo-skeletal (Superficial)	P	P	N		N	N	P	Note 1,2,3,6
	Intravascular								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel	P	P	N		N	N	P	Note 1,2,3,6
	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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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)									
Prescription USE (Per 21 CFR 801.109)									

Digital Ultrasonic Diagnostic Imaging System Indications For Use Format									
System:	DP-50/DP-50T/DP-50Expert/DP-50S/DP-50Pro Digital Ultrasonic Diagnostic Imaging System								
Transducer:	65C15EA								
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	P	P	N		N	N	P	Note 1,2,6
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	N		N	N	P	Note 1,2,6
	Small Organ (Specify**)								
	Neonatal Cephalic	P	P	N		N	N	P	Note 1,2,6
	Adult Cephalic	P	P	N		N	N	P	Note 1,2,6
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
Cardiac	Cardiac Adult								
	Cardiac Pediatric	P	P	N		N	N	P	Note 1,2,6
	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.									
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Prescription USE (Per 21 CFR 801.109)									

Digital Ultrasonic Diagnostic Imaging System Indications For Use Format									
System:	DP-50/DP-50T/DP-50Expert/DP-50S/DP-50Pro Digital Ultrasonic Diagnostic Imaging System								
Transducer:	35C20EA								
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 1,2,6
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	N	N	N		N	N	N	Note 1,2,6
	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	N	N	N		N	N	N	Note 1,2,6
	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.									
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Prescription USE (Per 21 CFR 801.109)									

Digital Ultrasonic Diagnostic Imaging System Indications For Use Format									
System:	DP-50/DP-50T/DP-50Expert/DP-50S/DP-50Pro Digital Ultrasonic Diagnostic Imaging System								
Transducer:	10L24EA								
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	P	P	N		N	N	P	Note 1,2,3,6
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	N		N	N	P	Note 1,2,3,6
	Small Organ (Specify**)	P	P	N		N	N	P	Note 1,2,3,6
	Neonatal Cephalic	P	P	N		N	N	P	Note 1,2,3,6
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	P	P	N		N	N	P	Note 1,2,3,6
	Musculo-skeletal (Superficial)	P	P	N		N	N	P	Note 1,2,3,6
	Intravascular								
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Peripheral vessel	Peripheral vessel	P	P	N		N	N	P	Note 1,2,3,6
	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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Digital Ultrasonic Diagnostic Imaging System Indications For Use Format									
System:	DP-50/DP-50T/DP-50Expert/DP-50S/DP-50Pro Digital Ultrasonic Diagnostic Imaging System								
Transducer:	65EB10EA								
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								
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	Small Organ (Specify**)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal	P	P	N		N	N	P	Note 1,2,6
	Trans-vaginal								
	Trans-urethral								
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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.									
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Digital Ultrasonic Diagnostic Imaging System Indications For Use Format									
System:	DP-50/DP-50T/DP-50Expert/DP-50S/DP-50Pro Digital Ultrasonic Diagnostic Imaging System								
Transducer:	65EC10ED								
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 1,2,6
	Abdominal								
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
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	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal	N	N	N		N	N	N	Note 1,2,6
	Trans-vaginal	N	N	N		N	N	N	Note 1,2,6
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Note 1: Tissue Harmonic Imaging.									
Note 2: Biopsy Guidance									
Note 3: iScape									
Note 4: TDI									
Note 5: Color M									
Note 6: Smart3D									
Note 7:4D(Real-time 3D)									
(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)									

Digital Ultrasonic Diagnostic Imaging System Indications For Use Format									
System:	DP-50/DP-50T/DP-50Expert/DP-50S/DP-50Pro Digital Ultrasonic Diagnostic Imaging System								
Transducer:	75LT38EA								
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 1,2,3,6
	Intra-operative (Specify*)	N	N	N		N	N	N	Note 1,2,3,6
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	N	N	N		N	N	N	Note 1,2,3,6
	Small Organ (Specify**)	N	N	N		N	N	N	Note 1,2,3,6
	Neonatal Cephalic	N	N	N		N	N	N	Note 1,2,3,6
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	N	N	N		N	N	N	Note 1,2,3,6
	Musculo-skeletal (Superficial)	N	N	N		N	N	N	Note 1,2,3,6
	Intravascular								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel	N	N	N		N	N	N	Note 1,2,3,6
	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.									
***Other use includes Urology.									
Note 1: Tissue Harmonic Imaging.									
Note 2: Biopsy Guidance									
Note 3: iScape									
Note 4: TDI									
Note 5: Color M									
Note 6: Smart3D									
Note 7:4D(Real-time 3D)									
(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)									

Digital Ultrasonic Diagnostic Imaging System Indications For Use Format									
System:	DP-50/DP-50T/DP-50Expert/DP-50S/DP-50Pro Digital Ultrasonic Diagnostic Imaging System								
Transducer:	75L53EA								
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	P	P	N		N	N	P	Note 1,2,3,6
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	N		N	N	P	Note 1,2,3,6
	Small Organ (Specify**)	P	P	N		N	N	P	Note 1,2,3,6
	Neonatal Cephalic	P	P	N		N	N	P	Note 1,2,3,6
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	P	P	N		N	N	P	Note 1,2,3,6
	Musculo-skeletal (Superficial)	P	P	N		N	N	P	Note 1,2,3,6
	Intravascular								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel	P	P	N		N	N	P	Note 1,2,3,6
	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.									
***Other use includes Urology.									
Note 1: Tissue Harmonic Imaging.									
Note 2: Biopsy Guidance									
Note 3: iScape									
Note 4: TDI									
Note 5: Color M									
Note 6: Smart3D									
Note 7:4D(Real-time 3D)									
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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)									
Prescription USE (Per 21 CFR 801.109)									

Digital Ultrasonic Diagnostic Imaging System Indications For Use Format									
System:	DP-50/DP-50T/DP-50Expert/DP-50S/DP-50Pro Digital Ultrasonic Diagnostic Imaging System								
Transducer:	D6-2EA								
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 1,2,7
	Abdominal	N	N	N		N	N	N	Note 1,2,7
	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.									
***Other use includes Urology.									
Note 1: Tissue Harmonic Imaging.									
Note 2: Biopsy Guidance									
Note 3: iScape									
Note 4: TDI									
Note 5: Color M									
Note 6: Smart3D									
Note 7:4D(Real-time 3D)									
(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).

The assigned 510(k) number is: K200979.

1. Submitter:

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Date Prepared: April 3, 2020

2. Device Name: DP-50/DP-50T/DP-50Expert/DP-50S/DP-50Pro Digital Ultrasonic Diagnostic Imaging 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. Main Predicate Device: DP-50 Digital Ultrasonic Diagnostic Imaging System

Classification

Regulatory Class: II

Review Category: Tier II

21 CFR 892.1560 Ultrasonic Pulsed Echo Imaging System (IYO)

21 CFR 892.1570 Diagnostic Ultrasound Transducer (ITX)

4. Device Description:

The DP-50/DP-50T/DP-50Expert/DP-50S/DP-50Pro Digital Ultrasonic Diagnostic Imaging System is a general purpose, portable, software controlled, ultrasonic diagnostic system. Its function is to acquire and display ultrasound data in B-Mode, M-Mode, PW-Mode, Color-Mode, Power/Dirpower Mode, THI, Smart3D, 4D, iScape, Biopsy Guidance 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, Convex array probe.

The software of DP-50/DP-50T/DP-50Expert/DP-50S/DP-50Pro Digital Ultrasonic Diagnostic Imaging System is based on the main predicate DP-50, and it has a Moderate level of concern.

5. Indications for Use:

The DP-50/DP-50T/DP-50Expert/DP-50S/DP-50Pro Digital Ultrasonic Diagnostic Imaging System is applicable for adults, pregnant women, pediatric patients and neonates. It is intended for use in fetal, abdominal, Intra-operative (abdominal, thoracic, and vascular), pediatric, small organ (breast, thyroid, testes, etc.), neonatal and adult cephalic, trans-rectal, trans-vaginal, musculo-skeletal (conventional, superficial), cardiac(adult, pediatric), peripheral vascular. The system is designed to be used by a trained operator in a clinical setting.

6. Summary of Modifications

- **Newly Added Models:**

  DP-50T，DP-50Expert，DP-50S，DP-50Pro;

- **Newly Added Transducers:**

  D6-2EA，65EC10ED，35C20EA，75LT38EA;

- **Newly Added Needle-guided Brackets:**

  NGB-003，NGB-010;

- **Main Added Features and Modifications:**

  1. Appearance change;
  2. Add PW mode to all transducers;
  3. Add Color mode to all transducers;
  4. Add Power mode to all transducers;
  5. Add 4D and Smart 3D;
  6. Add Free Xros M;
  7. Add iScape View;
  8. Add iLive;
  9. Add iWorks;
  10. Add Smart Face;
  11. Add Smart OB;
  12. Add Smart Bladder;
  13. Add iNeedle;
  14. Add iPage;
  15. Add HPRF;
  16. Add mobile trolley UMT-160 and UMT-170;
  17. Change the probe board;
  18. Add function of transducer element check.

7. Comparison with Predicate Devices:

The DP-50/DP-50T/DP-50Expert/DP-50S/DP-50Pro Digital Ultrasonic Diagnostic Imaging System is comparable with and substantially equivalent to these predicate devices:

Predicate Device	Manufacturer	Model	510(k) Control Number

1. Primary predicate device	Mindray	DP-50	K111435
2. Reference device	Mindray	Z6	K182603
3. Reference device	Mindray	Resona 7	K171233
4. Reference device	Mindray	DC-N2	K132779
5. Reference device	Mindray	DP-6900	K090912
6. Reference device	Mindray	DC-N3	K140030

- Below is comparative tables of new added special functions:

Items	**Subject Device DP-50/DP-50T/DP-50Expert/DP-50 S/DP-50Pro**	**Predicate Device Resona 7 (K171233)**	**S/ D**
4D	The probe performs the scanning automatically. During the scanning, the system renders 3D images in real time, and all 3D images are displayed in real time.	The probe performs the scanning automatically. During the scanning, the system renders 3D images in real time,and all 3D images are displayed in real time.	S
Conclusion	*These two devices both provide 4D function. The technological characteristics of the 4D function are the same. So they are substantial equivalent.*		
Smart 3D	The operator manually moves the probe to changes its position/angle when performing the scanning, the system carries out image rendering automatically, and then displays a frame of 3D image.	The operator manually moves the probe to changes its position/angle when performing the scanning, the system carries out image rendering automatically, and then displays a frame of 3D image.	S
Conclusion	*These two devices both provide Smart 3D function. The technological characteristics of the Smart 3D function are the same. So they are substantial equivalent.*		
Free Xros M	In the Anatomical M mode, you can manipulate the M-mark line to move to any position at desired angles. The system supports anatomical M scanning in 2D imaging modes(B, Color, Power mode)	In the Anatomical M mode, you can manipulate the M-mark line to move to any position at desired angles. The system supports anatomical M scanning in 2D imaging modes(B, Color, Power mode)	S
Conclusion	*These two devices both provide Free Xros M function. The technological characteristics of the Free Xros M function are the same. So they are substantial equivalent.*		

iLive	iLive brings a better imaging experience by adding a light rendering effect to the traditional method. It supports the global lighting mode as well as the partial scattering mode, allowing human tissue texture to be revealed more clearly.	iLive brings a better imaging experience by adding a light rendering effect to the traditional method. It supports the global lighting mode as well as the partial scattering mode, allowing human tissue texture to be revealed more clearly.	S
Conclusion	*These two devices both provide iLive function. The technological characteristics of the iLive function are the same. So they are substantial equivalent.*		
iWorks	Provide several step by step workflow protocols according to clinical operation custom. User can activate necessary display modes and image parameters, measurements and calculation items, add comments and pictograms as per the steps provided in the exam. This function reduces the operations, especially reduces the excessive number of control panel key strokes.	Provide several step by step workflow protocols according to clinical operation custom. User can activate necessary display modes and image parameters, measurements and calculation items, add comments and pictograms as per the steps provided in the exam. This function reduces the operations, especially reduces the excessive number of control panel key strokes.	S
Conclusion	*These two devices both provide iWorks function. The technological characteristics of the iWorks function are the same. So they are substantial equivalent.*		
iScape View	The iScape panoramic imaging feature extends your field of view by piecing together multiple B images into a single, extended B image. Use this feature, for example, to view a complete hand or thyroid.	The iScape panoramic imaging feature extends your field of view by piecing together multiple B images into a single, extended B image. Use this feature, for example, to view a complete hand or thyroid.	S
Conclusion	*These two devices both provide iScape function. The technological characteristics of the iScape function are the same. So they are substantial equivalent.*		
iNeedle	iNeedle makes needle display clearer in the course of biopsy or anesthesia by providing an additional deflection transmission.	iNeedle makes needle display clearer in the course of biopsy or anesthesia by providing an additional deflection transmission.	S
Conclusion	*These two devices both provide iNeedle function. The technological characteristics of the iNeedle function are the same. So they are substantial equivalent.*		
iPage	iPage is a new “Visualization” mode	iPage is a new “Visualization” mode	S

	for displaying sectional images. The data is presented as slices through the data set, which are parallel to each other. iPage is an option and is not available for Smart 3D images.	for displaying sectional images. The data is presented as slices through the data set, which are parallel to each other. iPage is an option and is not available for Smart 3D images.	
Conclusion	*These two devices both provide iPage function. The technological characteristics of the iPage function are the same. So they are substantial equivalent.*		
HPRF	HPRF function is used when detected velocities exceed the processing capabilities of the currently selected PW Doppler scale, or when the selected anatomical site is too deep for the selected PW Doppler scale. HPRF enhances the range of detecting high-velocity flow.	HPRF function is used when detected velocities exceed the processing capabilities of the currently selected PW Doppler scale, or when the selected anatomical site is too deep for the selected PW Doppler scale. HPRF enhances the range of detecting high-velocity flow.	S
Conclusion	*These two devices both provide HPRF function. The technological characteristics of the HPRF function are the same. So they are substantial equivalent.*		
Smart Face	This feature allows the system to recognize fetal face automatically and then display the face in a recommended viewing angle.	This feature allows the system to recognize fetal face automatically and then display the face in a recommended viewing angle.	S
Conclusion	*These two devices both provide Smart Face function. The technological characteristics of the Smart Face function are the same. So they are substantial equivalent.*		
Smart OB	The Smart OB is obstetric measurement tools. It is used to calculate the obstetric measurements.	The Smart OB is obstetric measurement tools. It is used to calculate the obstetric measurements.	S
Conclusion	*These two devices both provide Smart OB function. The technological characteristics of the Smart OB function are the same. So they are substantial equivalent.*		

Items	**Subject Device DP-50/DP-50T/DP-50Expert/DP-50S/DP-50Pro**	**Predicate Device DC-N3 (K140030)**	**S/D**
Smart Bladder	The Smart Bladder is provided to measure the volume of the urine in	The Smart Bladder is provided to measure the volume of the urine in	S

	the bladder automatically.	the bladder automatically.	
Conclusion	*These two devices both provide Smart Bladder function. The technological characteristics of the Smart Bladder function are the same. So they are substantial equivalent.*		

- Below is comparative tables of new added imaging modes:

Items	**Subject Device DP-50/DP-50T/DP-50Expert/DP-50S/DP-50Pro**	**Predicate Device DC-N2(K132779)**	**S/D**
PW mode to all transducers	PW (Pulsed Wave Doppler) mode is used to provide blood flow velocity and direction utilizing a real-time spectral display. The horizontal axis represents time, while the vertical axis represents Doppler frequency shift.	PW (Pulsed Wave Doppler) mode is used to provide blood flow velocity and direction utilizing a real-time spectral display. The horizontal axis represents time, while the vertical axis represents Doppler frequency shift.	S
Conclusion	*These two devices both provide PW mode. The technological characteristics of the PW mode are the same. So they are substantial equivalent.*		
Color mode to all transducers	The Color mode is used to detect color flow information, and the color is designed to judge the direction and speed of blood flow.	The Color mode is used to detect color flow information, and the color is designed to judge the direction and speed of blood flow.	S
Conclusion	*These two devices both provide Color mode. The technological characteristics of the Color mode are the same. So they are substantial equivalent.*		
Power mode to all transducers	Power mode provides a non-directional display of blood flow in the form of intensity as opposed to flow velocity. DirPower (Directional Power mode) provides additional information of flow direction towards or away from the probe.	Power mode provides a non-directional display of blood flow in the form of intensity as opposed to flow velocity. DirPower (Directional Power mode) provides additional information of flow direction towards or away from the probe.	S
Conclusion	*These two devices both provide Power mode. The technological characteristics of the Power mode are the same. So they are substantial equivalent.*		

Detailed information of newly added imaging modes to these transducers are as follows:

35C50EA

Model	35C50EA& DP-50/DP-50T/DP-50Expert/DP-50S/DP-50Pro	35C50EA & DC-N2 (K132779)	S/D
Manufacturer	Shenzhen Mindray Bio-Medical Electronics Co., Ltd.	Shenzhen Mindray Bio-Medical Electronics Co., Ltd.	/
510(K) Number	/	K132779	/
Indication(s) for use	Fetal Abdominal Pediatric Musculo-skeletal(Conventional)	Fetal Abdominal Pediatric Musculo-skeletal(Conventional) Peripheral vessel	S
Modes of operation	B/M/PWD/Color Doppler / Amplitude Doppler / B+M/PW+B /Color+B/ Power+B /PW+Color+B /Power+PW+B /THI/ Biopsy Guidance /Smart3D	B/M/PWD/Color Doppler / Amplitude Doppler / B+M/PW+B /Color+B/ Power+B /PW+Color+B /Power+PW+B /THI/ Biopsy Guidance/iScape /Smart3D	S
Is the acoustic output below Ispta.3 = 720mW/cm2 and either MI=1.9 or Isppa.3 =190W/cm2?	yes	yes	S
Acoustic output is measured and recorded according to the procedures in 510(k) guidance?	yes	yes	S
Geometrical shape	Convex	Convex	S

65C15EA

Model	65C15EA& DP-50/DP-50T/DP-50Expert/ DP-50S/DP-50Pro	65C15EA & DC-N2 (K132779)	S/D
Manufacturer	Shenzhen Mindray Bio-Medical	Shenzhen Mindray Bio-Medical	/

	Electronics Co., Ltd.	Electronics Co., Ltd.	
510(K) Number	/	K132779	/
Indication(s) for use	Abdominal Pediatric Neonatal Cephalic Adult Cephalic	Abdominal Pediatric Neonatal Cephalic Adult Cephalic	S
	Cardiac Pediatric	Cleared in K111435 already.	
Modes of operation	B/M/PWD/Color Doppler / Amplitude Doppler / B+M/PW+B /Color+B/ Power+B /PW+Color+B /Power+PW+B /THI/ Biopsy Guidance /Smart3D	B/M/PWD/Color Doppler / Amplitude Doppler / B+M/PW+B /Color+B/ Power+B /PW+Color+B /Power+PW+B /THI/ Biopsy Guidance/iScape /Smart3D	S
Is the acoustic output below Ispta.3 = 720mW/cm2 and either MI=1.9 or Isppa.3 =190W/cm2?	yes	yes	S
Acoustic output is measured and recorded according to the procedures in 510(k) guidance?	yes	yes	S
Geometrical shape	Convex	Convex	S

65EC10EA

Model	**65EC10EA& DP-50/DP-50T/DP-50Expert/ DP-50S/DP-50Pro**	**D6-2P& DC-N2 (K132779)**	**S/D**
Manufacturer	Shenzhen Mindray Bio-Medical Electronics Co., Ltd.	Shenzhen Mindray Bio-Medical Electronics Co., Ltd.	/
510(K) Number	/	K132779	/
Indication(s) for use	Fetal Trans-rectal Trans-vaginal	Fetal Trans-rectal Trans-vaginal Urology	S

Modes of operation	B/M/PWD/Color Doppler / Amplitude Doppler / B+M/PW+B /Color+B/ Power+B /PW+Color+B /Power+PW+B /THI/ Biopsy Guidance /Smart3D	B/M/PWD/Color Doppler / Amplitude Doppler / B+M/PW+B /Color+B/ Power+B /PW+Color+B /Power+PW+B /THI/ Biopsy Guidance/iScape /Smart3D	S
Is the acoustic output below Ispta.3 = 720mW/cm2 and either MI=1.9 or Isppa.3 =190W/cm2?	yes	yes	S
Acoustic output is measured and recorded according to the procedures in 510(k) guidance?	yes	yes	S
Geometrical shape	Convex	Convex	S

75L38EA

Model	**75L38EA& DP-50/DP-50T/DP-50Expert/DP-50S/DP-50Pro**	**75L38EA & DC-N2 (K132779)**	**S/D**
Manufacturer	Shenzhen Mindray Bio-Medical Electronics Co., Ltd.	Shenzhen Mindray Bio-Medical Electronics Co., Ltd.	/
510(K) Number	/	K132779	/
Indication(s) for use	Abdominal Pediatric Small Organ Neonatal Cephalic Musculo-skeletal(Conventional) Musculo-skeletal (Superficial) Peripheral vessel	Abdominal Pediatric Small Organ Neonatal Cephalic Musculo-skeletal(Conventional) Musculo-skeletal (Superficial) Peripheral vessel	S

Modes of operation	B/M/PWD/Color Doppler / Amplitude Doppler / B+M/PW+B /Color+B/ Power+B /PW+Color+B /Power+PW+B /THI/ Biopsy Guidance/iScape /Smart3D	B/M/PWD/Color Doppler / Amplitude Doppler / B+M/PW+B /Color+B/ Power+B /PW+Color+B /Power+PW+B /THI/ Biopsy Guidance/iScape /Smart3D	S
Is the acoustic output below Ispta.3 = 720mW/cm2 and either MI=1.9 or Isppa.3 =190W/cm2?	yes	yes	S
Acoustic output is measured and recorded according to the procedures in 510(k) guidance?	yes	yes	S
Geometrical shape	Linear	Linear	S

75L53EA

Model	**75L53EA& DP-50/DP-50T/DP-50Expert/DP-50S/DP-50Pro**	**75L38EA & DC-N2 (K132779)**	**S/D**
Manufacturer	Shenzhen Mindray Bio-Medical Electronics Co., Ltd.	Shenzhen Mindray Bio-Medical Electronics Co., Ltd.	/
510(K) Number	/	K132779	/
Indication(s) for use	Abdominal Pediatric Small Organ Neonatal Cephalic Musculo-skeletal(Conventional) Musculo-skeletal (Superficial) Peripheral vessel	Abdominal Pediatric Small Organ Neonatal Cephalic Musculo-skeletal(Conventional) Musculo-skeletal (Superficial) Peripheral vessel	S

Modes of operation	B/M/PWD/Color Doppler / Amplitude Doppler / B+M/PW+B /Color+B/ Power+B /PW+Color+B /Power+PW+B /THI/ Biopsy Guidance/iScape /Smart3D	B/M/PWD/Color Doppler / Amplitude Doppler / B+M/PW+B /Color+B/ Power+B /PW+Color+B /Power+PW+B /THI/ Biopsy Guidance/iScape /Smart3D	S
Is the acoustic output below Ispta.3 = 720mW/cm2 and either MI=1.9 or Isppa.3 =190W/cm2?	yes	yes	S
Acoustic output is measured and recorded according to the procedures in 510(k) guidance?	yes	yes	S
Geometrical shape	Linear	Linear	S

10L24EA

Model	**10L24EA& DP-50/DP-50T/DP-50Expert/DP-50S/DP-50Pro**	**10L24EA & DC-N2 (K132779)**	**S/D**
Manufacturer	Shenzhen Mindray Bio-Medical Electronics Co., Ltd.	Shenzhen Mindray Bio-Medical Electronics Co., Ltd.	/
510(K) Number	/	K132779	/
Indication(s) for use	Abdominal Pediatric Small Organ Neonatal Cephalic Musculo-skeletal(Conventional) Musculo-skeletal (Superficial) Peripheral vessel	Abdominal Pediatric Small Organ Neonatal Cephalic Musculo-skeletal(Conventional) Musculo-skeletal (Superficial) Peripheral vessel	S

Modes of operation	B/M/PWD/Color Doppler / Amplitude Doppler / B+M/PW+B /Color+B/ Power+B /PW+Color+B /Power+PW+B /THI/ Biopsy Guidance/iScape /Smart3D	B/M/PWD/Color Doppler / Amplitude Doppler / B+M/PW+B /Color+B/ Power+B /PW+Color+B /Power+PW+B /THI/ Biopsy Guidance/iScape /Smart3D	S
Is the acoustic output below Ispta.3 = 720mW/cm2 and either MI=1.9 or Isppa.3 =190W/cm2?	yes	yes	S
Acoustic output is measured and recorded according to the procedures in 510(k) guidance?	yes	yes	S
Geometrical shape	Linear	Linear	S

65EB10EA

Model	**65EB10EA& DP-50/DP-50T/DP-50Expert/ DP-50S/DP-50Pro**	**65EB10EA & DC-N2 (K132779)**	**S/D**
Manufacturer	Shenzhen Mindray Bio-Medical Electronics Co., Ltd.	Shenzhen Mindray Bio-Medical Electronics Co., Ltd.	/
510(K) Number	/	K132779	/
Indication(s) for use	Trans-rectal	Fetal Trans-rectal Trans-vaginal Urology	S

Modes of operation	B/M/PWD/Color Doppler / Amplitude Doppler / B+M/PW+B /Color+B/ Power+B /PW+Color+B /Power+PW+B /THI/ Biopsy Guidance /Smart3D	B/M/PWD/Color Doppler / Amplitude Doppler / B+M/PW+B /Color+B/ Power+B /PW+Color+B /Power+PW+B /THI/ Biopsy Guidance/iScape /Smart3D	S
Is the acoustic output below Ispta.3 = 720mW/cm2 and either MI=1.9 or Isppa.3 =190W/cm2?	yes	yes	S
Acoustic output is measured and recorded according to the procedures in 510(k) guidance?	yes	yes	S
Geometrical shape	Convex	Convex	S

- Below is comparative tables of new added transducers:

D6-2EA

Model	**D6-2EA& DP-50/DP-50T/DP-50Expert/ DP-50S/DP-50Pro**	**D6-2P&Z6 (K182603)**	**S/D**
Manufacturer	Shenzhen Mindray Bio-Medical Electronics Co., Ltd.	Shenzhen Mindray Bio-Medical Electronics Co., Ltd.	/
510(K) Number	/	K182603	/
Indication(s) for use	Fetal Abdominal	Fetal Abdominal	S

Modes of operation	B/M/PWD/Color Doppler / Amplitude Doppler / B+M/PW+B /Color+B/ Power+B /PW+Color+B /Power+PW+B /THI/Smart3D/4D	B/M/PWD/Color Doppler / Amplitude Doppler / B+M/PW+B /Color+B/ Power+B /PW+Color+B /Power+PW+B /THI/Smart3D/4D	S
Is the acoustic output below Ispta.3 = 720mW/cm2 and either MI=1.9 or Isppa.3 =190W/cm2?	yes	yes	S
Acoustic output is measured and recorded according to the procedures in 510(k) guidance?	yes	yes	S
Distance between adjacent elements(mm)	0.6048	0.6048	S
Geometrical shape	Convex	Convex	S
Array elements	128	128	S
Radius/Width(mm)	40	40	S
Axis size(mm)	11	11	S
Nominal frequency(MHz)	4.0	4.0	S

65EC10ED

Model	**65EC10ED& DP-50/DP-50T/DP-50Expert/ DP-50S/DP-50Pro**	**65EC10ED &DC-N2 (K132779)**	**S/D**
Manufacturer	Shenzhen Mindray Bio-Medical Electronics Co., Ltd.	Shenzhen Mindray Bio-Medical Electronics Co., Ltd.	/
510(K) Number	/	K132779	/
Indication(s) for use	Fetal Trans-rectal Trans-vaginal	Fetal Trans-rectal Trans-vaginal Urology	S

Modes of operation	B/M/PWD/Color Doppler / Amplitude Doppler / B+M/PW+B /Color+B/ Power+B /PW+Color+B /Power+PW+B /THI/ Biopsy Guidance /Smart3D	B/M/PWD/Color Doppler / Amplitude Doppler / B+M/PW+B /Color+B/ Power+B /PW+Color+B /Power+PW+B /THI/ Biopsy Guidance /Smart3D/iScape	S
Is the acoustic output below Ispta.3 = 720mW/cm2 and either MI=1.9 or Isppa.3 =190W/cm2?	yes	yes	S
Acoustic output is measured and recorded according to the procedures in 510(k) guidance?	yes	yes	S
Distance between adjacent elements(mm)	0.312	0.312	S
Geometrical shape	Convex	Convex	S
Array elements	80	80	S
Radius/Width(mm)	10	10	S
Axis size(mm)	5	5	S
Nominal frequency(MHz)	6.5	6.5	S

35C20EA

Model	**35C20EA& DP-50/DP-50T/DP-50Expert/ DP-50S/DP-50Pro**	**35C20EA & DC-N2 (K132779)**	**S/D**
Manufacturer	Shenzhen Mindray Bio-Medical Electronics Co., Ltd.	Shenzhen Mindray Bio-Medical Electronics Co., Ltd.	/
510(K) Number	/	K132779	/
Indication(s) for use	Abdominal Pediatric Cardiac Adult	Abdominal Pediatric Cardiac Adult Cardiac Pediatric	S

Modes of operation	B/M/PWD/Color Doppler / Amplitude Doppler / B+M/PW+B /Color+B/ Power+B /PW+Color+B /Power+PW+B /THI/ Biopsy Guidance /Smart3D	B/M/PWD/Color Doppler / Amplitude Doppler / B+M/PW+B /Color+B/ Power+B /PW+Color+B /Power+PW+B /THI/ Biopsy Guidance /Smart3D/iScape	S
Is the acoustic output below Ispta.3 = 720mW/cm2 and either MI=1.9 or Isppa.3 =190W/cm2?	yes	yes	S
Acoustic output is measured and recorded according to the procedures in 510(k) guidance?	yes	yes	S
Distance between adjacent elements(mm)	0.4	0.4	S
Geometrical shape	Convex	Convex	S
Array elements	80	80	S
Radius/Width(mm)	20	20	S
Axis size(mm)	12.4	12.4	S
Nominal frequency(MHz)	3.5	3.5	S

75LT38EA

Model	**75LT38EA& DP-50/DP-50T/DP-50Expert/ DP-50S/DP-50Pro**	**7LT4P & Z6 (K182603)**	**S/D**
Manufacturer	Shenzhen Mindray Bio-Medical Electronics Co., Ltd.	Shenzhen Mindray Bio-Medical Electronics Co., Ltd.	/
510(K) Number	/	K182603	/
Indication(s) for use	Abdominal Intra-operative Pediatric Small Organ Neonatal Cephalic Musculo-skeletal(Conventional)	Abdominal Intra-operative Pediatric Small Organ Neonatal Cephalic Musculo-skeletal(Conventional)	S

	Musculo-skeletal (Superficial) Peripheral vessel	Musculo-skeletal (Superficial) Peripheral vessel	
Modes of operation	B/M/PWD/Color Doppler / Amplitude Doppler / B+M/PW+B /Color+B/ Power+B /PW+Color+B /Power+PW+B /THI/ Biopsy Guidance /iScape /Smart3D	B/M/PWD/Color Doppler / Amplitude Doppler / B+M/PW+B /Color+B/ Power+B /PW+Color+B /Power+PW+B /THI/ Biopsy Guidance /iScape /Smart3D	S
Is the acoustic output below Ispta.3 = 720mW/cm2 and either MI=1.9 or Isppa.3 =190W/cm2?	yes	yes	S
Acoustic output is measured and recorded according to the procedures in 510(k) guidance?	yes	yes	S
Distance between adjacent elements(mm)	0.48	0.315	D
Geometrical shape	Linear	Linear	S
Array elements	80	128	D
Radius/Width(mm)	/	/	S
Axis size(mm)	4	4	S
Nominal frequency(MHz)	7.5	7.5	S

Note:

Due to new design, the distance between adjacent elements and array elements of 75LT38EA is different from 7LT4P. This difference does not influence the diagnostic, and use of the device. The added 75LT38EA has been tested under the IEC60601-1, IEC60601-1-2 etc. This difference does not influence the safety and effectiveness of this transducers.

Meaning of symbols used in the above table: S: Same D: Different

The DP-50/DP-50T/DP-50Expert/DP-50S/DP-50Pro Digital Ultrasonic Diagnostic Imaging System has the same technological characteristics, is comparable in key

safety and effectiveness features, and has the same intended uses and basic operating modes as the predicate devices. All systems transmit ultrasonic energy into patients and 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.

- Subject device

  The DP-50/DP-50T/DP-50Expert/DP-50S/DP-50Pro Digital Ultrasonic Diagnostic Imaging System has the similar intended uses as the predicated device DP-50 (K111435)

Subject Device **DP-50/DP-50T/DP-50Expert/DP-50S/DP-50Pro**	**Predicate device** **DP-50 (K111435)**
The Digital Ultrasonic Diagnostic Imaging 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, etc.), neonatal and adult cephalic, trans-rectal, trans-vaginal, musculo-skeletal(conventional, superficial), cardiac(pediatric), peripheral vascular .	The Digital Ultrasonic Diagnostic Imaging System is applicable for adults, pregnant women, pediatric and neonates. It is intended for use in fetal, abdominal, pediatric, small organ (breast, thyroid, testes, etc.), neonatal and adult cephalic, trans-rectal, trans-vaginal, musculo-skeletal(conventional, superficial), cardiac(pediatric), peripheral vascular .
Intra-operative (abdominal, thoracic, and vascular) ,cardiac(adult)	Cleared in Z6 (K182603)

- The acoustic power levels of DP-50/DP-50T/DP-50Expert/DP-50S/DP-50Pro are below the limits of FDA, which is the same as the predicated device DP-50 (K111435)
- The DP-50/DP-50T/DP-50Expert/DP-50S/DP-50Pro is designed in compliance with the FDA recognized electrical and physical safety standard, which is the same as the predicated device DP-50 (K111435)

  The DP-50/DP-50T/DP-50Expert/DP-50S/DP-50Pro has similar probes as the predicated device.

8. Non-clinical Tests:

The DP-50/DP-50T/DP-50Expert/DP-50S/DP-50Pro Digital Ultrasonic Diagnostic Imaging 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:

- 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
- IEC 62304: Medical device software - Software life cycle processes
- IEC 62366:Medical devices - application of usability engineering to medical devices
- IEC 60601-1-6: medical electrical equipment - part 1-6: general requirements for basic safety and essential performance - collateral standard: usability.
- 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

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

9. Clinical Studies

Not applicable. The subject of this submission, DP-50/DP-50T/DP-50Expert/DP-50S/DP-50Pro Digital Ultrasonic Diagnostic Imaging 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 DP-50/DP-50T/DP-50Expert/DP-50S /DP-50Pro Digital Ultrasonic Diagnostic Imaging System is substantially equivalent with respect to safety and effectiveness to devices currently cleared for market.