ShenZhen Mindray Bio-Medical Electronics Co., Ltd. April 2, 2020
℅ Shi Jufang
Engineer of Technical Regulation
Mindray Building, Keji 12th Road South
Hi-Tech Industrial Park
Shenzhen, Guangdong 518057
CHINA

Re: K200251
Trade/Device Name: Z5/Z50/Z50T/Z50S/Z50 Pro 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
Dated: January 20, 2020
Received: February 3, 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)*

K200251

Device Name
Z5/Z50/Z50T/Z50S/Z50 Pro Diagnostic Ultrasound System

Indications for Use *(Describe)*

Z5/Z50/Z50T/Z50S/Z50 Pro Diagnostic Ultrasound System is applicable for adults, pregnant women, pediatric patients and neonates. It is intended for use in Fetal, Abdominal, Pediatric, Musculo-skeletal（conventional, superficial）, Peripheral Vascular, Trans-rectal, Trans-vaginal, Small organ（breast, thyroid and testes）, Cephalic（neonatal and adult）, Cardiac（adult and pediatric）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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"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."

Diagnostic Ultrasound Indications for Use Format

System:	Z5/Z50/Z50T/Z50S/Z50 Pro 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	PW D	CW D	Color Doppler	Amplitude Doppler	Combined (specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	P	P	P		P	P	P	Note 1,2,3,6,7
	Abdominal	P	P	P		P	P	P	Note 1,2,3,6,7
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	P	Note 1,2,3,6
	Small Organ (Specify**)	P	P	P		P	P	P	Note 1,2,3,6
	Neonatal Cephalic	P	P	P		P	P	P	Note 1,2,3,6
	Adult Cephalic	P	P	P		P	P	P	Note 1,2,3,6
	Trans-rectal	P	P	P		P	P	P	Note 1,2,3,6
	Trans-vaginal	P	P	P		P	P	P	Note 1,2,3,6
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	P	P	P		P	P	P	Note 1,2,3,6
	Musculo-skeletal (Superficial)	P	P	P		P	P	P	Note 1,2,3,6
	Intravascular								
Cardiac	Cardiac Adult	P	P	P		P	P	P	Note 1,2,3,6
	Cardiac Pediatric	P	P	P		P	P	P	Note 1,2,3,6
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel	P	P	P		P	P	P	Note 1,2,3,6
	Other (Specify***)	P	P	P		P	P	P	Note 1,2,3,6

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)

Diagnostic Ultrasound Indications for Use Format									
System:	Z5/Z50/Z50T/Z50S/Z50 Pro Diagnostic Ultrasound 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	P		P	P	P	Note 1,2,3,6
	Abdominal	P	P	P		P	P	P	Note 1,2,3,6
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	P	Note 1,2,3,6
	Small Organ (Specify**)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	P	P	P		P	P	P	Note 1,2,3,6
	Musculo-skeletal (Superficial)								
	Intravascular								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel	P	P	P		P	P	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)									

Diagnostic Ultrasound Indications for Use Format									
System:	Z5/Z50/Z50T/Z50S/Z50 Pro Diagnostic Ultrasound 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	P	P	P		P	P	P	Note 1,2,3,6
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	P	Note 1,2,3,6
	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	P	P	P		P	P	P	Note 1,2,3,6
	Cardiac Pediatric	P	P	P		P	P	P	Note 1,2,3,6
	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.									
*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)									

Diagnostic Ultrasound Indications for Use Format									
System:	Z5/Z50/Z50T/Z50S/Z50 Pro Diagnostic Ultrasound 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	P		P	P	P	Note 1,2,3,6
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	P	Note 1,2,3,6
	Small Organ (Specify**)								
	Neonatal Cephalic	P	P	P		P	P	P	Note 1,2,3,6
	Adult Cephalic	P	P	P		P	P	P	Note 1,2,3,6
	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)									
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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)									
Prescription USE (Per 21 CFR 801.109)									

Diagnostic Ultrasound Indications for Use Format									
System:	Z5/Z50/Z50T/Z50S/Z50 Pro Diagnostic Ultrasound 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	P		P	P	P	Note 1,2,3,6
	Abdominal								
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify**)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal	P	P	P		P	P	P	Note 1,2,3,6
	Trans-vaginal	P	P	P		P	P	P	Note 1,2,3,6
	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***)	P	P	P		P	P	P	Note 1,2,3,6
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)									

Diagnostic Ultrasound Indications for Use Format									
System:	Z5/Z50/Z50T/Z50S/Z50 Pro Diagnostic Ultrasound 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	P		P	P	P	Note 1,2,3,6
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	P	Note 1,2,3,6
	Small Organ (Specify**)	P	P	P		P	P	P	Note 1,2,3,6
	Neonatal Cephalic	P	P	P		P	P	P	Note 1,2,3,6
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	P	P	P		P	P	P	Note 1,2,3,6
	Musculo-skeletal (Superficial)	P	P	P		P	P	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	P		P	P	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)									

Diagnostic Ultrasound Indications for Use Format

System:	Z5/Z50/Z50T/Z50S/Z50 Pro Diagnostic Ultrasound 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	P		P	P	P	Note 1,2,3,6
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	P	Note 1,2,3,6
	Small Organ (Specify**)	P	P	P		P	P	P	Note 1,2,3,6
	Neonatal Cephalic	P	P	P		P	P	P	Note 1,2,3,6
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	P	P	P		P	P	P	Note 1,2,3,6
	Musculo-skeletal (Superficial)	P	P	P		P	P	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	P		P	P	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)

Diagnostic Ultrasound Indications for Use Format									
System:	Z5/Z50/Z50T/Z50S/Z50 Pro Diagnostic Ultrasound 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.									
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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: K200251.

1. Submitter:

Shenzhen Mindray Bio-medical Electronics Co., LTD
Mindray Building, Keji 12th Road South, Hi-tech Industrial Park, Nanshan, Shenzhen, 518057, P. R. China
Tel: +86 755 8188 6293
Fax: +86 755 2658 2680

Contact Person:
Shi Jufang
Shenzhen Mindray Bio-medical Electronics Co., LTD
Mindray Building, Keji 12th Road South, Hi-tech Industrial Park,
Nanshan, Shenzhen, 518057, P. R. China

Date Prepared: January 20, 2020

2. Device Name: Z5/Z50/Z50T/Z50S/Z50 Pro 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:

The Z5/Z50/Z50T/Z50S/Z50 Pro Diagnostic Ultrasound 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.

4. Intended Use:

The Z5/Z50/Z50T/Z50S/Z50 Pro Diagnostic Ultrasound System is applicable for adults, pregnant women, pediatric patients and neonates. It is intended for use in Fetal, Abdominal, Pediatric, Musculo-skeletal（conventional, superficial）, Peripheral Vascular, Trans-rectal, Trans-vaginal, Small organ（breast, thyroid and testes）, Cephalic（neonatal and adult）, Cardiac（adult and pediatric）and Urology exams.

5. Summary of Modifications

- **Newly Added Models:**
  Z50, Z50T, Z50S, Z50 Pro;
- **Newly Added Transducers:**
  D6-2EA;
- **Main Added Features and Modifications:**
  1. Appearance change;
  2. Add host with three probe board;
  3. Add 4D and Smart 3D;
  4. Add Free Xros M;
  5. Add iLive;
  6. Add iWorks;
  7. Add iNeedle;
  8. Add Smart Face;
  9. Add Smart OB;
  10. Add mobile trolley UMT-170.

6. Comparison with Predicate Devices:

The Z5/Z50/Z50T/Z50S/Z50 Pro 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	Z5	K130695
2. Reference device	Mindray	Z6	K182603
3. Reference device	Mindray	DC-40	K183377

The Z5/Z50/Z50T/Z50S/Z50 Pro Diagnostic Ultrasound 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 Z5/Z50/Z50T/Z50S/Z50 Pro Diagnostic Ultrasound System has the same intended uses as the predicated device Z5 (K130695)

Subject Device **The Z5/Z50/Z50T/Z50S/Z50 Pro**	**Predicate device** **Z5 (K130695)**
The Diagnostic Ultrasound System is applicable for adults, pregnant women, pediatric patients and neonates. It is intended for use in Fetal, Abdominal, Pediatric, Musculo-skeletal （conventional, superficial）, Peripheral Vascular, Trans-rectal, Trans-vaginal,	The Diagnostic Ultrasound System is applicable for adults, pregnant women, pediatric and neonates. It is intended for use in Fetal, Abdominal, Pediatric, Musculo-skeletal (conventional, superficial), Peripheral Vascular, Trans-rectal, Trans-vaginal, Small organ

Small organ（breast, thyroid and testes）, Cephalic（neonatal and adult）, Cardiac（adult and pediatric）and Urology exams.	(breast, thyroid and testes), Cephalic (neonatal and adult), Cardiac (adult and pediatric) and Urology exams.

- The acoustic power levels of Z5/Z50/Z50T/Z50S/Z50 Pro are below the limits of FDA, which is the same as the predicated device Z5 (K130695)
- The Z5/Z50/Z50T/Z50S/Z50 Pro is designed in compliance with the FDA recognized electrical and physical safety standard, which is the same as the predicated device Z5 (K130695)

  The Z5/Z50/Z50T/Z50S/Z50 Pro has similar probes as the predicated device.

7. Non-clinical Tests:

The Z5/Z50/Z50T/Z50S/Z50 Pro Diagnostic Ultrasound System has been evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness as well as thermal, electrical and mechanical safety, and has been designed to conform with applicable medical safety standards. This device has been tested and evaluated under the following standards:

- 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.

8. Clinical Studies

Not applicable. The subject of this submission, Z5/Z50/Z50T/Z50S/Z50 Pro 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 Z5/Z50/Z50T/Z50S/Z50 Pro Diagnostic Ultrasound System is substantially equivalent with respect to safety and effectiveness to devices currently cleared for market.