Shenzhen Mindray Bio-Medical Electronics Co., Ltd. April 9, 2020
℅ Shi Jufang
Engineer of Technical Regulation
Keji 12th Road South, Hi-tech Industrial Park
Shenzhen, Guangdong 518057
CHINA

Re: K200001
Trade/Device Name: MX7/MX7T/Vaus7/Zeus/ME7/Anesus ME7/Anesus ME7T/MX8/ MX8T/ Vaus8/ME8 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: March 18, 2020
Received: March 23, 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)* **K200001**

Device Name
MX7/ MX7T/ Vaus7/ Zeus/ ME7/ Anesus ME7/ Anesus ME7T/ MX8/ MX8T/ Vaus8/ ME8 Diagnostic Ultrasound System

Indications for Use *(Describe)*

MX7/ MX7T/ Vaus7/ Zeus/ ME7/ Anesus ME7/ Anesus ME7T/ MX8/ MX8T/ Vaus8/ ME8 Diagnostic Ultrasound System is applicable for adults, pregnant women, pediatric patients and neonates. It is intended for use in ophthalmic, fetal, abdominal, pediatric, small organ(breast, thyroid, testes), neonatal cephalic,adult cephalic,trans-rectal, trans-vaginal, musculo-skeletal(conventional), musculo- skeletal(superficial), thoracic/pleural, cardiac adult, cardiac pediatric, peripheral vessel and urology exams.

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

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Diagnostic Ultrasound System Indications For Use Format

System: MX7/MX7T/Vaus7/Zeus/ME7/Anesus ME7/Anesus ME7T/MX8/MX8T/Vaus8/ME8 Diagnostic Ultrasound
Transducer: /
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic	N		N		N		N	
Fetal Imaging & Other	Fetal	N	N	N		N	N	N	Note 1,2,4,5,6
	Abdominal	N	N	N	N	N	N	N	Note 1,2,4,5,6,9,10
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	N	N	N	N	N	N	N	Note 1,2,4,5,6,10
	Small Organ (Specify**)	N	N	N		N	N	N	Note 1,2,~~4,~~5,6,7,10
	Neonatal Cephalic	N	N	N	N	N	N	N	Note 1,2,4,5,6
	Adult Cephalic	N	N	N	N	N	N	N	Note 1,2,4,5,6
	Trans-rectal	N	N	N		N	N	N	Note 1,2,4,5,6,7
	Trans-vaginal	N	N	N		N	N	N	Note 1,2,4,5,6,7
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	N	N	N		N	N	N	Note 1,2,4,5,6,7,10
	Musculo-skeletal (Superficial)	N	N	N		N	N	N	Note 1,2,~~4,~~5,6,7,10
	Intravascular								
	Thoracic/Pleural (Specify****)	N	N			N	N	N	Note 1,2,4,5,6,10
Cardiac	Cardiac Adult	N	N	N	N	N	N	N	Note 1,2,3,4,5,6,8
	Cardiac Pediatric	N	N	N	N	N	N	N	Note 1,2,3,4,5,6
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel	N	N	N		N	N	N	Note 1,2,4,5,6,~~7,~~10
	Other (Specify***)	N	N	N		N	N	N	Note 1,2,4,5,6,7

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.

****For detection of fluid and pleural motion/sliding.

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

Note 2: iScape

Note 3: TDI

Note 4: Color M

Note 5: Biopsy Guidance

Note 6: Smart 3D

Note 7: Strain Elastography

Note 8: Contrast imaging (Contrast agent for LVO)

Note 9: Contrast imaging (Contrast agent for Liver)

Note 10: eSpacial Navi

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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 System Indications For Use Format

System: MX7/MX7T/Vaus7/Zeus/ME7/Anesus ME7/Anesus ME7T/MX8/MX8T/Vaus8/ME8 Diagnostic Ultrasound
Transducer: C5-1s
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	N	N	N		N	N	N	Note 1,2,4,5,6
	Abdominal	N	N	N		N	N	N	Note 1,2,4,5,6,9
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	N	N	N		N	N	N	Note 1,2,4,5,6
	Small Organ (Specify**)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	N	N	N		N	N	N	Note 1,2,4,5,6
	Musculo-skeletal (Superficial)								
	Intravascular								
	Thoracic/Pleural (Specify****)	N	N			N	N	N	Note 1,2,4,5,6
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel	N	N	N		N	N	N	Note 1,2,4,5,6
	Other (Specify***)	N	N	N		N	N	N	Note 1,2,4,5,6

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.

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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 System Indications For Use Format

System: MX7/MX7T/Vaus7/Zeus/ME7/Anesus ME7/Anesus ME7T/MX8/MX8T/Vaus8/ME8 Diagnostic Ultrasound
Transducer: SC5-1Ns
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	N	N	N		N	N	N	Note 1,2,4,5,6
	Abdominal	N	N	N		N	N	N	Note 1,2,4,5,6,9
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	N	N	N		N	N	N	Note 1,2,4,5,6
	Small Organ (Specify**)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	N	N	N		N	N	N	Note 1,2,4,5,6
	Musculo-skeletal (Superficial)								
	Intravascular								
	Thoracic/Pleural (Specify****)	N	N			N	N	N	Note 1,2,4,5,6
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel	N	N	N		N	N	N	Note 1,2,4,5,6
	Other (Specify***)	N	N	N		N	N	N	Note 1,2,4,5,6

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 etc.

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Concurrence of CDRH, Office of Device Evaluation(ODE)

Prescription USE (Per 21 CFR 801.109)

Diagnostic Ultrasound System Indications For Use Format

System: MX7/MX7T/Vaus7/Zeus/ME7/Anesus ME7/Anesus ME7T/MX8/MX8T/Vaus8/ME8 Diagnostic Ultrasound
Transducer: V11-3s
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

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

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.

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Concurrence of CDRH, Office of Device Evaluation(ODE)

Prescription USE (Per 21 CFR 801.109)

Diagnostic Ultrasound System Indications For Use Format

System: MX7/MX7T/Vaus7/Zeus/ME7/Anesus ME7/Anesus ME7T/MX8/MX8T/Vaus8/ME8 Diagnostic Ultrasound
Transducer: V11-3Hs
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

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

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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Concurrence of CDRH, Office of Device Evaluation(ODE)

Prescription USE (Per 21 CFR 801.109)

Diagnostic Ultrasound System Indications For Use Format

System: MX7/MX7T/Vaus7/Zeus/ME7/Anesus ME7/Anesus ME7T/MX8/MX8T/Vaus8/ME8 Diagnostic Ultrasound
Transducer: L11-3VNs
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 1,2,6,10
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	N	N	N		N	N	N	Note 1,2,6,10
	Small Organ (Specify**)	N	N	N		N	N	N	Note 1,2,6,7,10
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	N	N	N		N	N	N	Note 1,2,6,10
	Musculo-skeletal (Superficial)	N	N	N		N	N	N	Note 1,2,6,10
	Intravascular								
	Thoracic/Pleural (Specify****)	N	N			N	N	N	Note 1,2,6,10
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel	N	N	N		N	N	N	Note 1,2,6,10
	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 Device Evaluation(ODE)

Prescription USE (Per 21 CFR 801.109)

Diagnostic Ultrasound System Indications For Use Format

System: MX7/MX7T/Vaus7/Zeus/ME7/Anesus ME7/Anesus ME7T/MX8/MX8T/Vaus8/ME8 Diagnostic Ultrasound
Transducer: L12-3RCs
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 1,2,5,6
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	N	N	N		N	N	N	Note 1,2,5,6
	Small Organ (Specify**)	N	N	N		N	N	N	Note 1,2,5,6,7
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	N	N	N		N	N	N	Note 1,2,5,6
	Musculo-skeletal (Superficial)	N	N	N		N	N	N	Note 1,2,5,6
	Intravascular								
	Thoracic/Pleural (Specify****)	N	N	N		N	N	N	Note 1,2,5,6
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel	N	N	N		N	N	N	Note 1,2,5,6
	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 etc.

**Small organ-breast, thyroid, testes.

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Concurrence of CDRH, Office of Device Evaluation(ODE)

Prescription USE (Per 21 CFR 801.109)

Diagnostic Ultrasound System Indications For Use Format

System: MX7/MX7T/Vaus7/Zeus/ME7/Anesus ME7/Anesus ME7T/MX8/MX8T/Vaus8/ME8 Diagnostic Ultrasound
Transducer: L13-3s
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	N		N		N		N	
Fetal Imaging & Other	Fetal								
	Abdominal	N	N	N		N	N	N	Note 1,2,5,6
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	N	N	N		N	N	N	Note 1,2,5,6
	Small Organ (Specify**)	N	N	N		N	N	N	Note 1,2,5,6,7
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	N	N	N		N	N	N	Note 1,2,5,6
	Musculo-skeletal (Superficial)	N	N	N		N	N	N	Note 1,2,5,6
	Intravascular								
	Thoracic/Pleural (Specify****)	N	N			N	N	N	Note 1,2,5,6
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel	N	N	N		N	N	N	Note 1,2,5,6
	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 etc.

**Small organ-breast, thyroid, testes.

***Other use includes Urology.

****For detection of fluid and pleural motion/sliding.

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

Note 2: iScape

Note 3: TDI

Note 4: Color M

Note 5: Biopsy Guidance

Note 6: Smart 3D

Note 7: Strain Elastography

Note 8: Contrast imaging (Contrast agent for LVO)

Note 9: Contrast imaging (Contrast agent for Liver)

Note 10: eSpacial Navi

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Concurrence of CDRH, Office of Device Evaluation(ODE)

Prescription USE (Per 21 CFR 801.109)

Diagnostic Ultrasound System Indications For Use Format

System: MX7/MX7T/Vaus7/Zeus/ME7/Anesus ME7/Anesus ME7T/MX8/MX8T/Vaus8/ME8 Diagnostic Ultrasound
Transducer: L13-3Ns
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	N		N		N		N	
Fetal Imaging & Other	Fetal								
	Abdominal	N	N	N		N	N	N	Note 1,2,5,6
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	N	N	N		N	N	N	Note 1,2,5,6
	Small Organ (Specify**)	N	N	N		N	N	N	Note 1,2,5,6,7
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	N	N	N		N	N	N	Note 1,2,5,6
	Musculo-skeletal	N	N	N		N	N	N	Note 1,2,5,6
	Intravascular								
	Thoracic/Pleural	N	N			N	N	N	Note 1,2,5,6
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel	N	N	N		N	N	N	Note 1,2,5,6
	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 etc.

**Small organ-breast, thyroid, testes.

***Other use includes Urology.

****For detection of fluid and pleural motion/sliding.

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

Note 2: iScape

Note 3: TDI

Note 4: Color M

Note 5: Biopsy Guidance

Note 6: Smart 3D

Note 7: Strain Elastography

Note 8: Contrast imaging (Contrast agent for LVO)

Note 9: Contrast imaging (Contrast agent for Liver)

Note 10: eSpacial Navi

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Concurrence of CDRH, Office of Device Evaluation(ODE)

Prescription USE (Per 21 CFR 801.109)

Diagnostic Ultrasound System Indications For Use Format

System: MX7/MX7T/Vaus7/Zeus/ME7/Anesus ME7/Anesus ME7T/MX8/MX8T/Vaus8/ME8 Diagnostic Ultrasound
Transducer: L14-6Ns
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	N		N		N		N	
Fetal Imaging & Other	Fetal								
	Abdominal	N	N	N		N	N	N	Note 1,2,5,6
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	N	N	N		N	N	N	Note 1,2,5,6
	Small Organ (Specify**)	N	N	N		N	N	N	Note 1,2,5,6,7
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal	N	N	N		N	N	N	Note 1,2,5,6
	Musculo-skeletal	N	N	N		N	N	N	Note 1,2,5,6
	Intravascular								
	Thoracic/Pleural	N	N			N	N	N	Note 1,2,5,6
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel	N	N	N		N	N	N	Note 1,2,5,6
	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 etc.									
**Small organ-breast, thyroid, testes.									
***Other use includes Urology.									
****For detection of fluid and pleural motion/sliding.									
Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.									
Note 2: iScape									
Note 3: TDI									
Note 4: Color M									
Note 5: Biopsy Guidance									
Note 6: Smart 3D									
Note 7: Strain Elastography									
Note 8: Contrast imaging (Contrast agent for LVO)									
Note 9: Contrast imaging (Contrast agent for Liver)									
Note 10: eSpacial Navi									
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Concurrence of CDRH, Office of Device Evaluation(ODE)									
Prescription USE (Per 21 CFR 801.109)									

Diagnostic Ultrasound System Indications For Use Format

System: MX7/MX7T/Vaus7/Zeus/ME7/Anesus ME7/Anesus ME7T/MX8/MX8T/Vaus8/ME8 Diagnostic Ultrasound
Transducer: L20-5s
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	N		N		N		N	
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	N	N	N		N	N	N	Note 1,2,6
	Small Organ (Specify**)	N	N	N		N	N	N	Note 1,2,6,7
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal	N	N	N		N	N	N	Note 1,2,6,7
	Musculo-skeletal	N	N	N		N	N	N	Note 1,2,6,7
	Intravascular								
	Thoracic/Pleural								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel	N	N	N		N	N	N	Note 1,2,6
	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 etc.

**Small organ-breast, thyroid, testes.

***Other use includes Urology.

****For detection of fluid and pleural motion/sliding.

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

Note 2: iScape

Note 3: TDI

Note 4: Color M

Note 5: Biopsy Guidance

Note 6: Smart 3D

Note 7: Strain Elastography

Note 8: Contrast imaging (Contrast agent for LVO)

Note 9: Contrast imaging (Contrast agent for Liver)

Note 10: eSpacial Navi

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Concurrence of CDRH, Office of Device Evaluation(ODE)

Prescription USE (Per 21 CFR 801.109)

Diagnostic Ultrasound System Indications For Use Format

System: MX7/MX7T/Vaus7/Zeus/ME7/Anesus ME7/Anesus ME7T/MX8/MX8T/Vaus8/ME8 Diagnostic Ultrasound
Transducer: P4-2s
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 1,2,4,5,6
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	N	N	N	N	N	N	N	Note 1,2,4,5,6
	Small Organ (Specify**)								
	Neonatal Cephalic	N	N	N	N	N	N	N	Note 1,2,4,5,6
	Adult Cephalic	N	N	N	N	N	N	N	Note 1,2,4,5,6
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal								
	Musculo-skeletal								
	Intravascular								
	Thoracic/Pleural	N	N			N	N	N	Note 1,2,4,5,6
Cardiac	Cardiac Adult	N	N	N	N	N	N	N	Note 1,2,3,4,5,6,8
	Cardiac Pediatric	N	N	N	N	N	N	N	Note 1,2,3,4,5,6
	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 etc.

**Small organ-breast, thyroid, testes.

***Other use includes Urology.

****For detection of fluid and pleural motion/sliding.

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

Note 2: iScape

Note 3: TDI

Note 4: Color M

Note 5: Biopsy Guidance

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Note 8: Contrast imaging (Contrast agent for LVO)

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Concurrence of CDRH, Office of Device Evaluation(ODE)

Prescription USE (Per 21 CFR 801.109)

Diagnostic Ultrasound System Indications For Use Format

System: MX7/MX7T/Vaus7/Zeus/ME7/Anesus ME7/Anesus ME7T/MX8/MX8T/Vaus8/ME8 Diagnostic Ultrasound
Transducer: SP5-1Ns
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 1,2,4,5,6
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	N	N	N	N	N	N	N	Note 1,2,4,5,6
	Small Organ (Specify**)								
	Neonatal Cephalic	N	N	N	N	N	N	N	Note 1,2,4,5,6
	Adult Cephalic	N	N	N	N	N	N	N	Note 1,2,4,5,6
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal								
	Musculo-skeletal								
	Intravascular								
	Thoracic/Pleural	N	N			N	N	N	Note 1,2,4,5,6
Cardiac	Cardiac Adult	N	N	N	N	N	N	N	Note 1,2,3,4,5,6,8
	Cardiac Pediatric	N	N	N	N	N	N	N	Note 1,2,3,4,5,6
	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 etc.

**Small organ-breast, thyroid, testes.

***Other use includes Urology.

****For detection of fluid and pleural motion/sliding.

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

Note 2: iScape

Note 3: TDI

Note 4: Color M

Note 5: Biopsy Guidance

Note 6: Smart 3D

Note 7: Strain Elastography

Note 8: Contrast imaging (Contrast agent for LVO)

Note 9: Contrast imaging (Contrast agent for Liver)

Note 10: eSpacial Navi

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Concurrence of CDRH, Office of Device Evaluation(ODE)

Prescription USE (Per 21 CFR 801.109)

K200001

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.

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: December 27, 2019

2. Device Name: MX7/ MX7T/ Vaus7/ Zeus/ ME7/ Anesus ME7/ Anesus ME7T/ MX8/ MX8T/ Vaus8/ ME8 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:

MX7/ MX7T/ Vaus7/ Zeus/ ME7/ Anesus ME7/ Anesus ME7T/ MX8/ MX8T/ Vaus8/ ME8 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, eSpacial Navi, Smart 3D mode, Strain Elastography, Contrast imaging (Contrast agent for Liver and LVO) 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 MX7/ MX7T/ Vaus7/ Zeus/ ME7/ Anesus ME7/ Anesus ME7T/ MX8/ MX8T/ Vaus8/ ME8 Diagnostic Ultrasound System is applicable for adults, pregnant women, pediatric patients and neonates. It is intended for use in ophthalmic, fetal, abdominal, pediatric, small organ (breast, thyroid, testes), neonatal cephalic, adult cephalic, trans-rectal, trans-vaginal, musculo-skeletal(conventional), musculo-skeletal(superficial), thoracic/pleural, cardiac adult, cardiac pediatric, peripheral vessel and urology exams.

5. Comparison with Predicate Devices:

MX7/ MX7T/ Vaus7/ Zeus/ ME7/ Anesus ME7/ Anesus ME7T/ MX8/ MX8T/ Vaus8/ ME8 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	M9	K171034
2. Reference device	Mindray	TE7	K180912
3. Reference device	Mindray	DC-70	K181637
4. Reference device	Mindray	DC-8	K170277

5. Reference device	Mindray	Resona 7	K171233
6. Reference device	GE Medical Systems Ultrasound and Primary Care Diagnostics, LLC	Venue	K180599

MX7/ MX7T/ Vaus7/ Zeus/ ME7/ Anesus ME7/ Anesus ME7T/ MX8/ MX8T/ Vaus8/ ME8 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 and predicate devices are based on the following same technological elements:

- The systems are all intended for ultrasound imaging, measurement and analysis of the human body and fluid for multiple clinical applications.
- The subject device and predicate M9 (K171034) have similar clinical indications for use however the proposed subject device has the ophthalmic and thoracic/pleural applications which has been cleared on predicate Venue (K180599).
- The systems are all mainly consisted of main units and transducers.
- The subject device and predicate M9 (K171034) have identical imaging modes, similar special functions however the proposed subject device has the Auto EF, R-VQS, RIMT, eSpacial Navi, Smart B-line, Smart VTI and Smart IVC functions which has been cleared on predicate DC-70(K181637)/Resona7(K171233)/TE7 (K180912)/ (Venue (K180599) .
- The subject device and predicate M9 (K171034) have similar capability in terms of comments, body marks, report, cine, file system and preset and other options however the proposed subject device supports iVocal which has been cleared on predicate TE7 (K180912).
- The system is manufactured with materials which have been evaluated and found to be safe for the intended use of the device.

- The systems have acoustic power levels which are below the applicable FDA limits.
- The subject device is designed in compliance with the FDA recognized electrical and physical safety standards, which are the same as the predicated device predicate M9 (K171034).

The following technological differences exist between the subject and predicate devices:

- Most of transducers of subject device and predicate M9 (K171034) and TE7 (K180912) are same, but rest transducers have same transducer types, modes of operation and applications compared with predicate device. And the subject device has been tested under the AAMI / ANSI ES60601-1, IEC60601-1-2 etc, they are safe and effective.
- The subject device is not intended to have intra-operative application, which is already cleared in the predicated M9 (K171034).

6. Non-clinical Tests:

MX7/ MX7T/ Vaus7/ Zeus/ ME7/ Anesus ME7/ Anesus ME7T/ MX8/ MX8T/ Vaus8/ ME8 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 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.
- ISO 10993-1 Fourth edition 2009-10-15, 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.

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing/ evaluation

The biocompatibility evaluation for the Diagnostic Ultrasound System was conducted in accordance with AAMI / ANSI / ISO 10993-1, biological evaluation of medical devices - part 1: evaluation and testing within a risk management process. The following biocompatibility tests are required:

- Haemolysis testing
- Acute systemic toxicity
- Cytotoxicity
- Intracutaneous reactivity
- Sensitization

For Diagnostic Ultrasound System, only probes and biopsy brackets will contact the patient's body. They are all passed biocompatibility testing/ evaluation.

Thermal, Mechanical and Electrical Safety

EMC testing is according to IEC 6060-1-2 and IEC 60601-2-37. All mechanical and electrical safety testing according to AAMI/ ANSI ES60601-1, Medical electrical equipment- Part 1: General requirements for basic safety and essential performance, were

performed in-house testing laboratory. Transducers temperature testing was conducted in home lab according to IEC 60601-2-37. None of the testing demonstrated by design characteristics violated the requirements of relevant standards.

Acoustic output power and Excessive temperature

Emitting energy has been evaluated during design phase. Acoustic output power has been measured and calculated after the design was finished. In addition the ALARA (as low as reasonably achievable) rule is also explained in detail in the operator's manual in order to guide the operator to use the system correctly.

Excessive temperature has been evaluated during design phase and tested after the design was finished. It meets the requirements in the harmonized standard IEC 60601-2-37 and FDA Guidance, "Marketing Clearance of Diagnostic Ultrasound Systems and Transducers" issue on June 27, 2019. Tests in the phase of design verification have proved that the Diagnostic Ultrasound System is safe and reliable.

Cleaning and Disinfection Effectiveness

The Diagnostic Ultrasound System with transducers require proper maintenance, inspection, cleaning, disinfection and sterilization to ensure maximum safety of operation and equipment protection. No device components are provided sterile to the user. The cleaning and disinfection effectiveness has been validated.

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." Issue on May 11, 2015. The level of concern for the Diagnostic Ultrasound System software was determined to be moderate in that failures may result in minor to moderate injury to the patient or to a user of the device, or a malfunction of, or a latent design flaw in, the software device lead to an erroneous diagnosis or a delay in delivery of appropriate medical care that would likely lead to Minor Injury.

7. Clinical Tests:

Not Applicable.

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 MX7/ MX7T/ Vaus7/ Zeus/ ME7/ Anesus ME7/ Anesus ME7T/ MX8/ MX8T/ Vaus8/ ME8 Diagnostic Ultrasound System is substantially equivalent with respect to safety and effectiveness to devices currently cleared for market.