Shenzhen Mindray Bio-Medical Electronics Co., LTD.
℅ Shi Jufang
Engineer of Technical Regulation
Mindray Building, Keji 12th Road South, Hi-tech Industrial Park
Nanshan, Shenzhen, 518057
P.R. CHINA

November 5, 2021

Re: K212900
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: September 5, 2021
Received: September 13, 2021

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 and Part 809); 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)*

K212900

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, intra-operative(abdominal, thoracic, and vascular) , trans-esoph(Cardiac) exams.

This device is a general purpose diagnostic ultrasound system intended for use by qualified and trained healthcare professionals for ultrasound imaging, measurement, display and analysis of the human body and fluid, which is intended to be used in a hospital or medical clinic.

Modes of operation include: B, M, PWD, CWD, Color Doppler, Amplitude Doppler, Combined mode(B+M, PW+B, Color+B, Power+B, PW+Color+B, Power+PW+B), Tissue Harmonic Imaging, iScape, TDI, color M, Smart 3D, Strain Elastography, Contrast imaging (Contrast agent for LVO), Contrast imaging (Contrast agent for Liver).

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.

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: K212900.

1. Submitter:

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Shenzhen Mindray Bio-medical Electronics Co., LTD
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Nanshan, Shenzhen, 518057, P. R. China

Date Prepared: September 5, 2021

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)

Main Predicate Device: MX7 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 MX7/MX7T/Vaus7/Zeus/ME7/Anesus ME7/Anesus ME7T/MX8/ MX8T/Vaus8/ME8 Diagnostic Ultrasound System is a general purpose, portable, software controlled, ultrasonic diagnostic system. Its function is to acquire and display ultrasound data in B, M, PWD, CWD, Color Doppler, Amplitude Doppler, Combined mode(B+M, PW+B, Color+B, Power+B, PW+Color+B, Power+PW+B), Tissue Harmonic Imaging, iScape, TDI, color M, Smart 3D, Strain Elastography, Contrast imaging (Contrast agent for LVO), Contrast imaging (Contrast agent for Liver) mode.

This system is a Track 3 device that employs an array of probes that include linear array, convex array and phased array probe.

4. Intended Use:

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, intra-operative(abdominal, thoracic, and vascular) , trans-esoph(Cardiac) exams.

This device is a general purpose diagnostic ultrasound system intended for use by qualified and trained healthcare professionals for ultrasound imaging, measurement,

display and analysis of the human body and fluid, which is intended to be used in a hospital or medical clinic.

Modes of operation include: B, M, PWD, CWD, Color Doppler, Amplitude Doppler, Combined mode(B+M, PW+B, Color+B, Power+B, PW+Color+B, Power+PW+B), Tissue Harmonic Imaging, iScape, TDI, color M, Smart 3D, Strain Elastography, Contrast imaging (Contrast agent for LVO), Contrast imaging (Contrast agent for Liver).

5. Summary of Modifications

- **Newly Added Clinical Applications:**
  Intra-operative(abdominal, thoracic, and vascular) , trans-esoph(Cardiac) exams;
- **Newly Added Transducers:**
  L9-3s、L12-3VNs、L16-4Hs、C11-3s、P10-4s、P7-3Ts、P8-3Ts、C5-2s、L12-4s、P8-2s、CW2s;
- **Newly Added Needle-guided Brackets:**
  NGB-015、NGB-018、NGB-034;
- **Main Added Features:**
  1. Add Auto GA
  2. Add Smart FHR OB1
  3. Add Smart Bladder
  4. Add Auto DFR
- **Other Changes:**
  1. Add mobile trolley MT2
  2. Add CPP

6. Comparison with Predicate Devices:

The 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	MX7	K200001
2. Reference device	Mindray	M9	K210416
3. Reference device	Mindray	TE7	K203391
4. Reference device	Mindray	Resona R9	K202785
5. Reference device	Mindray	M7	K172970

The MX7/MX7T/Vaus7/Zeus/ME7/Anesus ME7/Anesus ME7T/MX8/ MX8T/Vaus8/ME8 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 subject device and predicate MX7 (K200001) have similar clinical indications for use however the proposed subject device has the intra-operative (abdominal, thoracic, and vascular) and trans-esoph (Cardiac) applications which has been cleared on predicate TE7 (K203391)

Items	**Subject Device MX7/MX7T/Vaus7/Zeus/ME7/Anesus ME7/Anesus ME7T/MX8/ MX8T/Vaus8 /ME8**	**Predicate device MX7 (K200001)& TE7 (K203391)**	**S/D**

Intended Use	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, intra-operative(abdominal, thoracic, and vascular) , trans-esoph(Cardiac) exams. This device is a general purpose diagnostic ultrasound system intended for use by qualified and trained healthcare professionals for ultrasound imaging, measurement, display and analysis of the human body and fluid, which is intended to be used in a hospital or medical clinic.	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. TE7/TE5/TE7 Max/ TE5 Max/TE9 Diagnostic Ultrasound System is applicable for adults, pregnant women, pediatric patients and neonates. It is intended for use in fetal, Laparoscopic, abdominal,Intra-operative(abdominal, thoracic, and vascular), Pediatric ,small organ(breast, thyroid, testes), neonatal and adult cephalic,trans-esoph. (Cardiac), trans-rectal, trans-vaginal,	S

	Modes of operation include: B, M, PWD, CWD, Color Doppler, Amplitude Doppler, Combined mode(B+M, PW+B, Color+B, Power+B, PW+Color+B, Power+PW+B), Tissue Harmonic Imaging, iScape, TDI, color M, Smart 3D, Strain Elastography, Contrast imaging (Contrast agent for LVO), Contrast imaging (Contrast agent for Liver).	musculo-skeletal(conventional, superficial), urology,Peripheral vessel, Adult and Pediatric cardiac, ophthalmic, Thoracic/Pleural exams. This device is a general purpose diagnostic ultrasound system intended for use by qualified and trained healthcare professionals for ultrasound imaging, measurement, display and analysis of the human body and fluid, which is intended to be used in a hospital or medical clinic. Modes of operation include: B, M, PWD, CWD, Color Doppler, Amplitude Doppler, Combined mode(B+M, PW+B, Color+B, Power+B, PW+Color+B, Power+PW+B), Tissue Harmonic Imaging, Contrast imaging (Contrast agent for LVO),TDI,Color M, Smart 3D,Contrast imaging (Contrast agent for Liver) and iScape View.	

Note:

1. The intended use of subject device is covered by predicate device MX7 (K200001) except intra-operative (abdominal, thoracic, and vascular) and trans-esoph (Cardiac) applications. But the predicate device TE7 (K203391) has intra-operative (abdominal, thoracic, and vascular) and trans-esoph (Cardiac) application.
2. According to the requirements of FDA Guidance, “Marketing Clearance of Diagnostic

Ultrasound Systems and Transducers, June 27, 2019" (and following its numbering scheme)，add modes of operation, operator qualification and device use settings in the Indications for use

- The subject device and predicate MX7 (K200001) have identical imaging modes, similar special functions, however the proposed subject device has the Auto GA、Auto DFR functions which have been cleared in predicate M9 (K210416), and the Smart FHR OB1、Smart Bladder functions have been cleared in TE7(K203391).
- The subject device has similar probes as the predicate MX7 (K200001) however the proposed subject device has the L9-3s、L12-3VNs、L16-4Hs、C11-3s、P10-4s、P7-3Ts、P8-3Ts、C5-2s、L12-4s、P8-2s、CW2s, but they can be substantial equivalent with MX7 (K200001) , M9 (K210416), TE7(K203391), Resona R9 (K202785), and M7 (K172970).
- The acoustic power levels of subject device are below the limits of FDA, which is the same as the predicated device MX7 (K200001).
- The subject device is designed in compliance with the FDA recognized electrical and physical safety standard, which is the same as the predicated device MX7 (K200001).

7. Non-clinical Tests:

The 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 designed to conform with applicable medical safety standards. This device has been tested and evaluated under 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 Fifth edition 2018-08, 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.

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, MX7/MX7T/Vaus7/Zeus/ME7/Anesus ME7/Anesus ME7T/MX8/ MX8T/Vaus8/ME8 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 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 device MX7

(K200001) .