



September 12, 2024

Shenzhen Mindray Bio-Medical Electronics Co., LTD.
Tang Jing
Regulatory Specialist
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Shenzhen, Guangdong 518057
CHINA

Re: K241432

Trade/Device Name: MX7/MX7T/Vaus7/Zeus/ME7/Anesus ME7/ AnesusME7T/ MX7P/ MX7W/
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: May 20, 2024

Received: August 15, 2024

Dear Tang Jing:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and

production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Marjan Nabili -S for

Yanna Kang, Ph.D.

Assistant Director

Mammography and Ultrasound Team

DHT8C: Division of Radiological

Imaging and Radiation Therapy Devices

OHT8: Office of Radiological Health

Office of Product Evaluation and Quality

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K241432

Device Name

MX7/MX7T/Vaus7/Zeus/ME7/Anesus ME7/ AnesusME7T/ MX7P/ MX7W/MX8/MX8T/Vaus8/ME8 Diagnostic Ultrasound System

Indications for Use (Describe)

MX7/MX7T/Vaus7/Zeus/ME7/Anesus ME7/ AnesusME7T/MX7P/MX7W/MX8/MX8T/Vaus8/ME8 Diagnostic Ultrasound System is intended 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), transesoph(Cardiac) exams. Modes of operation include: B, M, PWD, CWD, Color Doppler, Power 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, 4D(Real-time 3D), Strain Elastography, Contrast imaging (Contrast agent for LVO), Contrast imaging (Contrast agent for Liver). 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.

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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K241432

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).

1. Submitter

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Date Prepared: May 19, 2024

2. Device Name

MX7/MX7T/Vaus7/Zeus/ME7/Anesus ME7/AnesusME7T/MX7P/MX7W/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. Predicate devices

MX7 series Diagnostic Ultrasound System is comparable with and substantially equivalent to the predicate devices listed below. MX7 (K212900) is the main predicate device.

Device	Manufacturer	Model	510(k) Number
1. Main predicate device	Mindray	MX7	K212900
2. Reference device	Mindray	M9	K230768
3. Reference device	Mindray	Resona I8W	K240115

The result shows the conformance of subject device to the predicate devices.

Regulation name and code:

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)

4. Device Description:

The MX7/MX7T/Vaus7/Zeus/ME7/Anesus ME7/AnesusME7T/MX7P/MX7W/MX8/MX8T/Vaus8/ME8 Diagnostic Ultrasound System is a general purpose, mobile, software controlled, ultrasonic diagnostic system. Its function is to acquire and display ultrasound images.

Modes of operation include: B, M, PWD, CWD, Color Doppler, Power 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, 4D(Real-time 3D), Strain Elastography, Contrast imaging (Contrast agent for LVO), Contrast imaging (Contrast agent for Liver).

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. The device can also measure anatomical structures and offer analysis packages to provide information based on which the competent health care professionals can make the diagnosis.

5. Intended Use:

MX7/MX7T/Vaus7/Zeus/ME7/Anesus ME7/AnesusME7T/MX7P/MX7W/MX8/MX8T/Vaus8/ME8 Diagnostic Ultrasound System is intended 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), transesoph(Cardiac) exams.

Modes of operation include: B, M, PWD, CWD, Color Doppler, Power 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, 4D(Real-time 3D), Strain Elastography, Contrast imaging (Contrast agent for LVO), Contrast imaging (Contrast agent for Liver).

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.

6. Comparison with Predicate Device:

The device is comparable with and substantially equivalent to the predicate device mentioned in “*Predicate Devices*” with regards to intended use, imaging modes, features and functions and technological characteristics.

- All systems transmit ultrasonic energy into patients, perform post processing of received echoes to generate on screen display of anatomic structures and fluid flow within the body.
- All systems allow for specialized measurements of structures and flow, as well as calculations.
- The device has the same intended uses as the predicated device MX7 (K212900) except 4D (Real-time 3D) mode. At the same time, M9 has the 4D (Real-time 3D) mode instead.
- The patient contact materials of the new transducers of subject device are the same as predicate device.
- The acoustic power levels of the device are below the limits of FDA, which are the same as the predicated device MX7 (K212900).
- The device is designed in compliance with the FDA recognized electrical and physical safety standards, which are the same as the predicated device MX7 (K212900).
- The device has the equivalent features and functions as the predicated device. Among these features, the 4D function in proposed MX7 series has been cleared in M9 (K230768).
- The device has the equivalent features and functions as the predicated devices. Among these features, the ilive supported in proposed MX7 series has been cleared in Resona I8W (K240115).

7. Non-clinical Tests:

MX7/MX7T/Vaus7/Zeus/ME7/Anesus ME7/AnesusME7T/MX7P/MX7W/MX8/MX8T/Vaus8/ME8 Diagnostic Ultrasound System has been evaluated for acoustic output, bio-compatibility, cleaning and disinfection effectiveness as well as thermal, electrical and mechanical safety, and this device has been designed to conform with applicable medical safety standards.

This device has been tested and evaluated under the following standards:

- NEMA UD 2-2004 (R2009), acoustic output measurement standard for diagnostic ultrasound equipment revision 3.
- ANSI AAMI ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 &

A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021] Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD) [Including Amendment 2 (2021)].

- IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.
- IEC TR 60601-4-2 Edition 1.0 2016-05 Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems
- IEC 60601-1-6 Edition 3.2 2020-07 CONSOLIDATED VERSION, Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability.
- 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.
- ISO 14971 Third Edition 2019-12, 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 62304 Edition 1.1 2015-06, medical device software - software life cycle processes.
- IEC 62366-1 Edition 1.1 2020-06 CONSOLIDATED VERSION, Medical devices - Part 1: Application of usability engineering to medical devices.

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/AnesusME7T/MX7P/MX7W/MX8/MX8T/Vaus8/ME8 Diagnostic Ultrasound System, does not require clinical studies to support substantial equivalence.

9. Summary

Based on the performance data as documented in the study, MX7/MX7T/Vaus7/Zeus/ME7/Anesus ME7/AnesusME7T/MX7P/MX7W/MX8/MX8T/Vaus8/ME8 Diagnostic Ultrasound System was found to have a safety and effectiveness profile that is similar to the predicate device.

10. 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 "Medical devices—Quality management systems". The device conforms to applicable medical device safety standards. Therefore, MX7/MX7T/Vaus7/Zeus/ME7/Anesus ME7/AnesusME7T/MX7P/MX7W/MX8/MX8T/Vaus8/ME8 Diagnostic Ultrasound System is substantially equivalent with respect to safety and effectiveness to the predicate device.