



Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
% Hao Yixuan
Engineer of Technical Regulation
Keji 12th Road South, Hi-tech Industrial Park
Shenzhen, Guangdong 518057
CHINA

November 16, 2021

Re: K212265

Trade/Device Name: TEX20/TEX20 Pro/TEX20S/TEX20T/TEX20 Exp/TEX20 Elite Diagnostic
Ultrasound System, TEX10/ TEX10 Pro/TEX10S/TEX10T/TEX10 Exp/TEX10
Elite/TE X/TE X Lite 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 30, 2021

Received: October 12, 2021

Dear Hao Yixuan:

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

Indications for Use

510(k) Number (if known)

K212265

Device Name

TEX20/TEX20 Pro/TEX20S/TEX20T/TEX20 Exp/TEX20 Elite/TEX10/TEX10 Pro/TEX10S/TEX10T/TEX10 Exp/TEX10 Elite/TE X/TE X Lite Diagnostic Ultrasound System

Indications for Use (Describe)

TEX20/TEX20 Pro/TEX20S/TEX20T/TEX20 Exp/TEX20 Elite/TEX10/TEX10 Pro/TEX10S/TEX10T/TEX10 Exp/TEX10 Elite/TE X/TE X Lite Diagnostic Ultrasound System is applicable for adults, pregnant women, pediatric patients and neonates. It is intended for use in Ophthalmic, fetal, abdominal, Intra-operative (abdominal, thoracic, and vascular), Laparoscopic, pediatric, small organ (breast, thyroid, testes), neonatal and adult cephalic, trans-rectal, trans-vaginal, musculo-skeletal (conventional, superficial), Thoracic/Pleural (For detection of fluid and pleural motion/sliding.), adult and pediatric cardiac, trans-esoph. (Cardiac), peripheral vessel, and urology exams.

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, Smart3D, iScape View, TDI, Color M, Strain Elastography, Contrast imaging (Contrast agent for LVO), and 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.

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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: K212265

1. Submitter

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Shenzhen, 518057, P. R. China

Date Prepared: July 15, 2021

2. Device Name

TEX20/TEX20 Pro/TEX20S/TEX20T/TEX20 Exp/TEX20 Elite/TEX10/ TEX10
Pro/TEX10S/TEX10T/TEX10 Exp/TEX10 Elite/TE X/TE X Lite 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

TEX20 series Diagnostic Ultrasound System is comparable with and substantially equivalent to the predicate devices listed below. TE7 is the main predicate devices.

Device	Manufacturer	Model	Device Class	Product Code	510K Number
1. Primary predicate device	Mindray	TE7	II	IYN, IYO, ITX	K203391
2. Reference device	Mindray	Resona I9	II	IYN, IYO, ITX,	K210699
3. Reference device	Mindray	MX7	II	IYN, IYO, ITX	K200001
4. Reference device	Mindray	M9	II	IYN, IYO, ITX	K210416
5. Reference device	Mindray	Resona 7	II	IYN, IYO, ITX	K202785

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 TEX20/TEX20 Pro/TEX20S/TEX20T/TEX20 Exp/TEX20 Elite/TEX10/ TEX10 Pro/TEX10S/TEX10T/TEX10 Exp/TEX10 Elite/TE X/TE X Lite Diagnostic Ultrasound System is a general purpose, mobile, software controlled, ultrasonic diagnostic system. Its function is to acquire and display ultrasound images in 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, Smart3D, iScape View, TDI, Color M, Strain Elastography, Contrast imaging (Contrast agent for LVO), and Contrast imaging (Contrast agent for Liver).

The TEX20/TEX20 Pro/TEX20S/TEX20T/TEX20 Exp/TEX20 Elite/TEX10/TEX10 Pro/TEX10S/TEX10T/TEX10 Exp/TEX10 Elite/TE X/TE X Lite Diagnostic Ultrasound System 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:

The TEX20/TEX20 Pro/TEX20S/TEX20T/TEX20 Exp/TEX20 Elite/TEX10/TEX10 Pro/TEX10S/TEX10T/TEX10 Exp/TEX10 Elite/TE X/TE X Lite Diagnostic Ultrasound System is applicable for adults, pregnant women, pediatric patients and neonates. It is intended for use in Ophthalmic, fetal, abdominal, Intra-operative (abdominal, thoracic, and vascular), Laparoscopic, pediatric, small organ(breast, thyroid, testes), neonatal and adult cephalic, trans-rectal, trans-vaginal, musculo-skeletal(conventional, superficial),

Thoracic/Pleural (For detection of fluid and pleural motion/sliding.), adult and pediatric cardiac, trans-esoph. (Cardiac), peripheral vessel, and urology exams.

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, Smart3D, iScape View, TDI, Color M, Strain Elastography, Contrast imaging (Contrast agent for LVO), and Contrast imaging (Contrast agent for Liver).

6. Comparison with Predicate Devices:

Subject device TEX20/TEX20 Pro/TEX20S/TEX20T/TEX20 Exp/TEX20 Elite/TEX10/ TEX10 Pro/TEX10S/TEX10T/TEX10 Exp/TEX10 Elite/TE X/TE X Lite Diagnostic Ultrasound System is comparable with and substantially equivalent to these predicate devices mentioned in 3. *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 onscreen display of anatomic structures and fluid flow within the body. All systems allow for specialized measurements of structures and flow, as well as calculations.
- Subject device TEX20/TEX20 Pro/TEX20S/TEX20T/TEX20 Exp/TEX20 Elite/TEX10/ TEX10 Pro/TEX10S/TEX10T/TEX10 Exp/TEX10 Elite/TE X/TE X Lite Diagnostic Ultrasound System has the same intended uses as the primary predicated device TE7 (K203391) except the mode of operation Strain Elastography, which has been cleared on predicate device Resona I9(K210699)
- The patient contact materials of the transducers and needle-guided brackets of subject device TEX20/TEX20 Pro/TEX20S/TEX20T/TEX20 Exp/TEX20 Elite/TEX10/ TEX10 Pro/TEX10S/TEX10T/TEX10 Exp/TEX10 Elite/TE X/TE X Lite Diagnostic Ultrasound System are the same to the predicate devices or tested under ISO 10993-1.
- The acoustic power levels of TEX20/TEX20 Pro/TEX20S/TEX20T/TEX20 Exp/TEX20 Elite/TEX10/ TEX10 Pro/TEX10S/TEX10T/TEX10 Exp/TEX10 Elite/TE X/TE X Lite are below the limits of FDA, which are the same as the primary predicated device TE7 (K203391).

- The TEX20/TEX20 Pro/TEX20S/TEX20T/TEX20 Exp/TEX20 Elite/TEX10/TEX10 Pro/TEX10S/TEX10T/TEX10 Exp/TEX10 Elite/TE X/TE X Lite is designed in compliance with the FDA recognized electrical and physical safety standards, which are the same as the primary predicated device TE7 (K203391).
- The TEX20/TEX20 Pro/TEX20S/TEX20T/TEX20 Exp/TEX20 Elite/TEX10/TEX10 Pro/TEX10S/TEX10T/TEX10 Exp/TEX10 Elite/TE X/TE X Lite has the equivalent features and functions as the predicated device. Among these features, the Auto DFR supported in proposed TEX20 series has been cleared in predicate device M9(K210416), the Smart Caliper and Smart Trace have been cleared in predicate device Resona I9(K210699).

For the differences compared to the predicate devices:

- The TEX20/TEX20 Pro/TEX20S/TEX20T/TEX20 Exp/TEX20 Elite/TEX10/TEX10 Pro/TEX10S/TEX10T/TEX10 Exp/TEX10 Elite/TE X/TE X Lite **introduces new software and hardware options** which in the below table that used as the enhancement based on the cleared functions to facilitate users or intended to support interconnecting information, no new intended use is added. Besides, the related verification/validation testing and risk analysis have been conducted and the results demonstrated the requirements for these new software and hardware options have been met.

Printer bracket	It is used for holding the printer
Rear storage bin	It is used for keeping the cases, towelette, etc.
Air Charge Module	Configured with the air station to charge the main unit.
Air Probe Charging Holder	It is used to charge wireless probe.
Air station	Cover wired power into wireless to provide power for Air Charge Module
iVocal Plus Microphone Array	The iVocal Plus is an improvement of iVocal (cleared in K210699), which both enables the system to perform operations through vocal commands and through tapping icons on the touch screen. The iVocal Plus Microphone array is a hardware used with iVocal Plus, it consists of microphone arrays (including wireless transceivers) and USB cables.
X-Link	The Ultrasound System supports interconnecting information with the bedside device through X-Link. The

	interconnection function of X-Link mainly includes: Obtaining data: The data of the same patient are matched through network connection; Using data: Real-time data are obtained and displayed in combination with ultrasound image data; Storing and reviewing data: The data are stored in combination with the ultrasound image data and can be reviewed on the ultrasound device.
ClamAV	It is an antivirus software
Smart Nerve	It is an AI (artificial intelligence) based feature. It is used to recognize the interscalene and supraclavicular brachial plexus. It is intended for visualization purpose only and not intended for live guidance during interventional procedure.

7. Non-clinical Tests:

The TEX20/TEX20 Pro/TEX20S/TEX20T/TEX20 Exp/TEX20 Elite/TEX10/TEX10 Pro/TEX10S/TEX10T/TEX10 Exp/TEX10 Elite/TE X/TE X Lite Diagnostic Ultrasound System has been evaluated for acoustic output, biocompatibility, 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.
- 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 disturbances - Requirements and tests
- 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.
- 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 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 62304 Edition 1.1 2015-06, medical device software - software life cycle processes.
- IEC 62366-1 Edition 1.0 2015-02 Medical devices - Part 1: Application of usability engineering to medical devices [Including CORRIGENDUM 1 (2016)].

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, TEX20/TEX20 Pro/TEX20S/TEX20T/TEX20 Exp/TEX20 Elite/TEX10/ TEX10 Pro/TEX10 / TEX10T/TEX10 Exp/TEX10 Elite/TE X/TE X Lite Diagnostic Ultrasound System, does not require clinical studies to support substantial equivalence.

9. Summary

Based on the performance data as documented in the study, the TEX20/TEX20 Pro/TEX20S/TEX20T/TEX20 Exp/TEX20 Elite/TEX10/ TEX10 Pro/TEX10S/TEX10T/TEX10 Exp/TEX10 Elite/TE X/TE X Lite 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 quality systems. The device conforms to applicable medical device safety standards. Therefore, the TEX20/TEX20 Pro/TEX20S/TEX20T/TEX20 Exp/TEX20 Elite/TEX10/ TEX10 Pro/TEX10S/TEX10T/TEX10 Exp/TEX10 Elite/TE X/TE X Lite Diagnostic Ultrasound System is substantially equivalent with respect to safety and effectiveness to its primary predicate device TE7.