September 16, 2024

Shenzhen Mindray Bio-medical Electronics Co., Ltd.
Zhang Yuxi
Engineer of Technical Regulation
Mindray Building, Keji 12th Road South,
Hi-tech Industrial Park, Nanshan
Shenzhen, Guangdong 518057
CHINA

Re: K241201
Trade/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/Anesus TEX20 Pro/Eagus TEX20/Eagus TEX20T/Eagus TEX21/Eagus TEX21T/Eros/TE X Plus/Anesus TEX10 Pro/TEX9U/TEX9M/Eagus TEX11/Eagus TEX11T/Eagus TEX10/Eagus TEX10T/Eagus TEX/Ares 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: April 30, 2024
Received: August 16, 2024

Dear Zhang Yuxi:

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,

Yanna S. Kang -S

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K241201

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/Anesus TEX20 Pro/Eagus TEX20/Eagus TEX20T/Eagus TEX21/Eagus TEX21T/Eros/TE X Plus/Anesus TEX10 Pro/TEX9U/TEX9M/Eagus TEX11/Eagus TEX11T/Eagus TEX10/Eagus TEX10T/Eagus TEX/Ares Diagnostic Ultrasound System

Indications for Use *(Describe)*
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 TEX20/TEX20 Pro/TEX20S/TEX20T/TEX20 Exp/TEX20 Elite/TEX10/TEX10 Pro/TEX10S/TEX10T/TEX10 Exp/TEX10 Elite/TE X/TE X Lite/Anesus TEX20 Pro/Eagus TEX20/Eagus TEX20T/Eagus TEX21/Eagus TEX21T/Eros/TE X Plus/Anesus TEX10 Pro/TEX9U/TEX9M/Eagus TEX11/Eagus TEX11T/Eagus TEX10/Eagus TEX10T/Eagus TEX/Ares 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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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 is: K241201

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:

Jin Jiahong

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: April 30, 2024

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/Anesus TEX20 Pro/Eagus TEX20/Eagus TEX20T/Eagus TEX21/Eagus TEX21T/Eros/TE X Plus/Anesus TEX10 Pro/TEX9U/TEX9M/Eagus TEX11/Eagus TEX11T/Eagus

TEX10/Eagus TEX10T/Eagus TEX/Ares 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:

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

Device	Manufacturer	Model	Device Class	Product Code	510K Number
1. Primary predicate device	Mindray	TEX20	II	IYN, IYO, ITX	K220242
2. Reference device	Mindray	Consona N9	II	IYN, IYO, ITX，	K221300
3. Reference device	Mindray	Resona I9	II	IYN, IYO, ITX	K210699
4. Reference device	Mindray	MX7	II	IYN, IYO, ITX	K212900
5. Reference device	Butterfly	iQ	II	IYN, IYO, ITX	K202406

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

Regulation name and code

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 TEX20/TEX20 Pro/TEX20S/TEX20T/TEX20 Exp/TEX20 Elite/TEX10/TEX10 Pro/TEX10S/TEX10T/TEX10 Exp/TEX10 Elite/TE X/TE X Lite/Anesus TEX20 Pro/Eagus TEX20/Eagus TEX20T/Eagus TEX21/Eagus TEX21T/Eros/TE X Plus/Anesus TEX10 Pro/TEX9U/TEX9M/Eagus TEX11/Eagus TEX11T/Eagus TEX10/Eagus TEX10T/Eagus TEX/Ares 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/Anesus TEX20 Pro/Eagus TEX20/Eagus TEX20T/Eagus TEX21/Eagus TEX21T/Eros/TE X Plus/Anesus TEX10 Pro/TEX9U/TEX9M/Eagus TEX11/Eagus TEX11T/Eagus TEX10/Eagus TEX10T/Eagus TEX/Ares 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.

4. Intended Use:

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 TEX20/TEX20 Pro/TEX20S/TEX20T/TEX20 Exp/TEX20 Elite/TEX10/TEX10 Pro/TEX10S/TEX10T/TEX10 Exp/TEX10 Elite/TE X/TE X Lite/Anesus TEX20 Pro/Eagus TEX20/Eagus TEX20T/Eagus TEX21/Eagus TEX21T/Eros/TE X Plus/Anesus TEX10 Pro/TEX9U/TEX9M/Eagus TEX11/Eagus TEX11T/Eagus TEX10/Eagus TEX10T/Eagus TEX/Ares 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).

5. 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/Anesus TEX20 Pro/Eagus TEX20/Eagus TEX20T/Eagus TEX21/Eagus TEX21T/Eros/TE X Plus/Anesus TEX10 Pro/TEX9U/TEX9M/Eagus TEX11/Eagus TEX11T/Eagus TEX10/Eagus TEX10T/Eagus TEX/Ares 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.

As compared with the primary predicate device TEX20 in K220242, the subject device has the modifications described as following.

New added features	
1	Add new transducers L15-3RCs，L16-3RCs，SC10-2RCs，L24-6RCs，L24-6Hs，SP5-1Ns，SC5-1Ns，i5M，ELC13-4s.
2	Add Contrast imaging (Contrast agent for Liver) to L12-3RCs.
3	Add new Software Options Smart VTI Plus, Smart Bladder, iClear+, Respiratory wave.
The other change	
4	Add ePanel, VA Grid, footswitch (MKF 2 1PW/1PW-MED GP26)
5	Change the name of Amplitude Doppler to Power Doppler.

The TEX20/TEX20 Pro/TEX20S/TEX20T/TEX20 Exp/TEX20 Elite/TEX10/TEX10 Pro/TEX10S/TEX10T/TEX10 Exp/TEX10 Elite/TE X/TE X Lite/Anesus TEX20 Pro/Eagus TEX20/Eagus TEX20T/Eagus TEX21/Eagus TEX21T/Eros/TE X Plus/Anesus TEX10 Pro/TEX9U/TEX9M/Eagus TEX11/Eagus TEX11T/Eagus TEX10/Eagus TEX10T/Eagus TEX/Ares Diagnostic Ultrasound System has the similar 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.

- The subject device and predicate TEX20(K220242) have same clinical indications for use.
- The subject device and predicate TEX20(K220242) have identical imaging modes, same special functions, however the proposed subject device has the Smart Bladder functions which have been cleared in predicate Consona N9 (K221300). iClear+ functions which have been cleared in predicate Resona I9(K221300)
- The acoustic power levels of subject device are below the limits of FDA, which is the same as the predicated device TEX20(K220242).
- The patient contact materials of the transducers and needle-guided brackets of subject device are the same to the predicate devices or tested under ISO 10993-1.
- The subject device is designed in compliance with the FDA recognized electrical and physical safety standards, which are the same as the primary predicated device TEX20(K220242).

6. 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/Anesus TEX20 Pro/Eagus TEX20/Eagus TEX20T/Eagus TEX21/Eagus TEX21T/Eros/TE X Plus/Anesus TEX10 Pro/TEX9U/TEX9M/Eagus TEX11/Eagus TEX11T/Eagus TEX10/Eagus TEX10T/Eagus TEX/Ares 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 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 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.

7. Clinical Studies

Not applicable. The subject of this submission, TEX20/TEX20 Pro/TEX20S/TEX20T/TEX20 Exp/TEX20 Elite/TEX10/TEX10 Pro/TEX10S/TEX10T/TEX10 Exp/TEX10 Elite/TE X/TE X Lite/Anesus TEX20 Pro/Eagus TEX20/Eagus TEX20T/Eagus TEX21/Eagus TEX21T/Eros/TE X Plus/Anesus TEX10 Pro/TEX9U/TEX9M/Eagus TEX11/Eagus TEX11T/Eagus TEX10/Eagus TEX10T/Eagus TEX/Ares 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 TEX20/TEX20 Pro/TEX20S/TEX20T/TEX20 Exp/TEX20 Elite/TEX10/TEX10 Pro/TEX10S/TEX10T/TEX10 Exp/TEX10 Elite/TE X/TE X Lite/Anesus TEX20 Pro/Eagus TEX20/Eagus TEX20T/Eagus TEX21/Eagus TEX21T/Eros/TE X Plus/Anesus TEX10 Pro/TEX9U/TEX9M/Eagus TEX11/Eagus TEX11T/Eagus TEX10/Eagus TEX10T/Eagus TEX/Ares Diagnostic Ultrasound System is substantially equivalent with respect to demonstrates substantial equivalence to predicate device.