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

Re: K220051
Trade/Device Name: TE Air 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: December 31, 2021
Received: January 6, 2022

March 4, 2022

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,

Jessica Lamb, Ph.D.
Assistant 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)*

K220051

Device Name

TE Air Diagnostic Ultrasound System

Indications for Use *(Describe)*

TE Air Diagnostic Ultrasound System is applicable for adults, pregnant women, pediatric patients and neonates. It is intended for use in abdominal, pediatric , thoracic/pleural (For detection of fluid and pleural motion/sliding.), adult and pediatric cardiac, neonatal and adult cephalic, and urology 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, Color Doppler, Amplitude Doppler, Combined mode(Color+B, Power+B), Tissue Harmonic Imaging, and TDI.

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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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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: K220051.

## 1. Submitter:

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**Contact Person:**

Shi Jufang

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**Date Prepared:** December 31, 2021

## 2. Device Name: TE Air 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 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 TE Air Diagnostic Ultrasound System is a general purpose, software controlled, ultrasonic diagnostic system. Its function is to acquire and display ultrasound data in B, M, PWD, Color Doppler, Amplitude Doppler, Combined mode (Color+B, Power+B), Tissue Harmonic Imaging, and TDI mode.

TE Air consists of an app which can be installed on iOS devices, and probes which use wireless technology for communication.

This system is a Track 3 device that employs phased array probes.

## 4. Intended Use:

TE Air Diagnostic Ultrasound System is applicable for adults, pregnant women, pediatric patients and neonates. It is intended for use in abdominal, pediatric ,

thoracic/pleural (For detection of fluid and pleural motion/sliding.), adult and pediatric cardiac, neonatal and adult cephalic, and urology 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, Color Doppler, Amplitude Doppler, Combined mode (Color+B, Power+B), Tissue Harmonic Imaging, and TDI.

## 5. Comparison with Predicate Devices:

The TE Air Diagnostic Ultrasound System is comparable with and substantially equivalent to these predicate devices:

| Device | Manufacturer | Model | 510(k) Number |
|---|---|---|---|
| 1. Primary predicate device | Mindray | TEX20 | K212265 |
| 2. Reference device | Mindray | MX7 | K212900 |
| 3. Reference device | Butterfly Network | Butterfly iQ | K202406 |

The TE Air 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.

| Items | Subject Device<br>TE Air | Predicate device<br>TEX20<br>(K212265) | S/D |
|---|---|---|---|
| Indications for use | Diagnostic Ultrasound System is applicable for adults, pregnant women, pediatric patients and neonates.<br><br>It is intended for use in abdominal, pediatric , thoracic/pleural (For detection of fluid and pleural motion/sliding.), adult and pediatric cardiac, neonatal and adult cephalic, and urology exams. | Diagnostic Ultrasound System is applicable for adults, pregnant women, pediatric patients and neonates.<br><br>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 | S |
| Modes of operation | Modes of operation include: B, M, PWD, Color Doppler, Amplitude Doppler, Combined mode (Color+B, Power+B), Tissue Harmonic Imaging, and TDI. | 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, | S |

| | | | |
|---|---|---|---|
| | | iScape View, TDI, Color M, Strain Elastography, Contrast imaging (Contrast agent for LVO), and Contrast imaging (Contrast agent for Liver). | |
| From the above comparison, the intended use of TE Air is covered by TEX20. | | | |

- Subject device

  The subject device and predicate TEX20 (K212265) have same clinical indications for use.
- The subject device and predicate TEX20 (K212265) have identical imaging modes, same special functions, however the proposed subject device has the Auto EF、Smart Bladder functions which have been cleared in predicate MX7 (K212900) .
- The acoustic power levels of subject device are below the limits of FDA, which is the same as the predicated device TEX20 (K212265).
- The proposed TE Air has a software app which can be installed on user's mobile device that provides some of the processing and uses the screen of the mobile device as the display like is done for cleared Butterfly iQ (K202406).

## 6. Non-clinical Tests:

The TE Air 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, TE Air 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 TE Air Diagnostic Ultrasound System is substantially equivalent with respect to safety and effectiveness to predicate device.