Shenzhen Mindray Bio-Medical Electronics Co., LTD.
% Ma Chao
Engineer of Technical Regulation
Keji 12th Road South, Hi-Tech Industrial Park
Shenzhen, Guangdong 518057
CHINA

March 23, 2021

Re: K203391
Trade/Device Name: TE7/TE5/TE7 Max/TE5 Max/TE9 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: January 22, 2021
Received: January 28, 2021

Dear Ma Chao:

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)*

K203391

Device Name
TE7/TE5/TE7 Max/ TE5 Max/TE9 Diagnostic Ultrasound System

Indications for Use *(Describe)*

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, 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.

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: _K203391__.

1. **Submitter:**

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Date Prepared: March 22, 2021

2. **Device Name:** TE7/TE5/TE7 Max/ TE5 Max/TE9 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:**

TE7/TE5/TE7 Max/ TE5 Max/TE9 is a software controlled, ultrasonic diagnostic system. Its function is to acquire and display ultrasound data in B-Mode, M-Mode, PW-Mode, CW-mode, Color-Mode , 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. This system is a Track 3 device that employs an array of probes that include Linear array, Convex array, Phased array and Volume probe.

4. **Intended Use:**

The 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, musculoskeletal (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.

5. Summary of Modifications

- **New Added Transducers and Needle-guided bracket:**
  Transducers: L12-3VNs, LAP13-4Cs, C9-3Ts, SP5-1Ns, SC5-1Ns, P8-2Ts and P8- 3Ts;
  Needle-guided bracket: NGB-043, NGB-044;
- **New added Clinical Application**
  Thoracic/Pleural, Laparoscopic
- **Modification**
  Textual modification of the probe model-"L12-3RC" modified to "L12-3RCs"
- **Main Added Features:**

  - **New applications are added to the transducers:**

  1. Add ophthalmic application to L11-3VNs, L12-3RCs and L12-3VNs;
  The ophthalmic application has already been cleared with L12-4s in the predicate device TE7/TE5(K180912).
  2. Add the CW to the fetal Application for P4-2s;
  The fetal application has already been cleared with SP5-1s in the predicate device TE7/TE5(K180912).
  3. **Add Abdominal application to L20-5s**;
  The abdominal application has already been cleared with L13-3s in the predicate device MX7 (K200001)
  4. Add Fetal application to L9-3s;
  The fetal application has already been cleared with L9-3U in the predicate device Resona 7 (K171233).
  5. Add Smart 3D function to L7-3s、L14-6s、7LT4s、L14-5sp、L20-5s、7L4s、L9-3s、L11-3VNs、L12-3RCs、L14-5Ws、L12-3VNs;
  By using the Smart 3D function, the operator moves the probe to change its position/angle when performing the scanning. After the scanning, the system carries out image reconstruction, and then displays a single frame of 3D image. This feature has been cleared with L16-4Hs in the predicate device M9 (K171034).
  6. Add LVO mode to 7LT4s;
  LVO is an exam mode for Left Ventricular Contrast Imaging. This feature has been cleared with L10-5 in predicate device ZS3 (K192410).

- **New Features:**

7.Add iScape View;

It extends your field of view by piecing together multiple B images into a single, extended B image. The feature has been cleared on the predicate device M9 (K171034).

8. **Add Smart IVC**;

Smart IVC is used to automatically measure the IVC inner diameter and calculate the change rate in the B mode image.The feature has been cleared on the predicate device MX7 (K200001).

9. Add Smart VTI;

Smart VTI is used to calculate the CO (cardiac output) of the LVOT (left ventricular output tract), so as to quickly evaluate the cardiac function. The feature has been cleared on the predicate device MX7 (K200001).

10. Add Smart B-Line;

Smart B-line is used to detect the B line of the lung in B mode. It supports B-line detecting in both real-time and freeze modes.The feature has been cleared on the predicate device MX7 (K200001).

11. Add EPSS;

It measures the distance between point E and Interventricular Septum when mitral valve is fully open. The feature has been cleared on the predicate device MX7 (K200001).

12. Add Smart trace;

It helps the operator to trace the contour of the normal anatomical regions by automatically recognizing the margin of the target and measures the lengths of major axis, minor axis, area and circumference of the closed region. This feature is similar to the cleared feature *Trace* on the predicate device Resona 7 (K171233) .

13. Add Auto GA;

After acquired image(s) of gastric antrum, by freezing image and tapping the Auto GA button, the feature shows boundary of gastric antrum and calculates the area of gastric antrum. This feature is similar to the feature *Area trace* on the predicate device TE7/TE5 (K180912);

14. Add Smart Bladder;

Smart Bladder is used to measure the volume of the urine in the bladder, which has been cleared on the predicate device DC-40(K183377).

15. Add Smart FHR OB1;

Smart FHR OB1 is to measure the fetal heart rate automatically. It is similar to the cleared feature *OB_FHR (M*) on the predicate device Resona 7 (K171233).

16. Add transducer element check

This function is used to check the condition of transducer elements to evaluate the probe performance.

- **New accessories**

17. Add UMT-400plus trolley

This trolley is used for supporting the main unit of ultrasound system.

- **Operating system upgrade**

Win 7 upgrade to win 10.

6. Comparison with Predicate Devices:

TE7/TE5/TE7 Max/ TE5 Max/TE9 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	TE7	K180912
2. Reference device	Mindray	ZS3, z.one pro	K192410
3. Reference device	Mindray	MX7	K200001
4. Reference device	Mindray	M9	K171034
5. Reference device	Mindray	Resona 7	K171233
6. Reference device	Mindray	DC-40	K183377

TE7/TE5/TE7 Max/ TE5 Max/TE9 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

  TE7/TE5/TE7 Max/ TE5 Max/TE9 has the similar intended uses as the predicated device TE7/TE5 (K180912)

Subject Device TE7/TE5/TE7 Max/ TE5 Max/TE9	Predicate device TE7/TE5 (K180912)
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, musculoskeletal (conventional, superficial), urology, Peripheral vessel, Adult and Pediatric cardiac, ophthalmic, Thoracic/Pleural exams	The TE7/TE5 Diagnostic Ultrasound System is applicable for adults, pregnant women, pediatric patients and neonates. It is intended for use in fetal, abdominal, intra-operative (abdominal, thoracic, and vascular), Pediatric, small organ (breast, thyroid, testes), neonatal and adult cephalic, trans-esoph. (cardiac), trans-rectal, trans-vaginal, musculoskeletal (conventional, superficial), urology, peripheral vessel, adult and pediatric cardiac, ophthalmic, exams.

- The acoustic power levels of TE7/TE5/TE7 Max/ TE5 Max/TE9 are below the limits of FDA, which is the same as the predicated device TE7/TE5 (K180912).
- TE7/TE5/TE7 Max/ TE5 Max/TE9 is designed in compliance with the FDA recognized electrical and physical safety standard, which is the same as the predicated device TE7/TE5 (K180912)

- The materials of probes and needle-guided brackets of TE7/TE5/TE7 Max/ TE5 Max/TE9 are the same to the predicate device or tested under ISO 10993-1.

7. Non-clinical Tests:

TE7/TE5/TE7 Max/ TE5 Max/TE9 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: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
- IEC 60601-1-2: Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests (Edition 3)
- IEC 60601-2-37: Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
- IEC 62304: Medical device software - Software life cycle processes
- IEC 62366: Medical devices - application of usability engineering to medical devices
- IEC 60601-1-6: medical electrical equipment - part 1-6: general requirements for basic safety and essential performance - collateral standard: usability
- ISO14971: Medical devices - Application of risk management to medical devices
- ISO 10993-1 Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process.

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, TE7/TE5/TE7 Max/ TE5 Max/TE9 Diagnostic Ultrasound System, does not require clinical studies to support substantial equivalence.

9. 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 TE7/TE5/TE7 Max/ TE5 Max/TE9 Diagnostic Ultrasound System is substantially equivalent with respect to safety and effectiveness to devices currently cleared for market.