December 3, 2025

Shenzhen Mindray Bio-medical Electronics Co., Ltd.
Tang Jing
Technical Regulatory Affairs, Technical Regulation Department
Mindray Building, Keji 12th Road South,
Hi-tech Industrial Park, Nanshan
Shenzhen, Guangdong 518057
CHINA

Re: K251601
Trade/Device Name: Hepatus 7/Hepatus 6/Hepatus 5/Hepatus 7S/Hepatus 6S/Hepatus 5S/Hepatus7T/Hepatus 6T/Hepatus 5T/Fibrous 7/Fibrous 6/Fibrous 5 Diagnosic 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: November 7, 2025
Received: November 7, 2025

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K251601

Device Name
Hepatus 7/Hepatus 6/Hepatus 5/Hepatus 7S/Hepatus 6S/Hepatus 5S/Hepatus 7T/Hepatus 6T/Hepatus 5T/Fibrous 7/Fibrous 6/Fibrous 5 Diagnostic Ultrasound System

Indications for Use *(Describe)*
Hepatus 7/Hepatus 6/Hepatus 5/Hepatus 7S/Hepatus 6S/Hepatus 5S/Hepatus 7T/Hepatus 6T/Hepatus 5T/Fibrous 7/ Fibrous 6/Fibrous 5 Diagnostic Ultrasound System is applicable for adults, pregnant women, pediatric patients and neonates. It is intended for use in fetal, abdominal, Pediatric, small organ (breast, thyroid, testes), Neonatal Cephalic, Adult Cephalic, musculo-skeletal (conventional), musculo- skeletal (superficial), thoracic/pleural, Cardiac Adult, Cardiac Pediatric and Peripheral vessel exams.
It is intended to provide 50Hz shear wave speed measurements (ViTE: Visual Transient Elastography) and estimates of tissue stiffness as well as 3.5 MHz ultrasound coefficient of attenuation (LiSA: Liver Ultra-Sound Attenuation) in internal structures of the body.
It is also intended to measure spleen stiffness using ViTE at 100 Hz shear wave frequency.
The liver stiffness measurement by ViTE may aid the physician in determining the likelihood of cirrhosis and may be used, taken in context with other clinical and laboratory data, as an aid in the assessment of liver fibrosis.
The coefficient of attenuation measurement by LiSA may be used, taken in context with other clinical and laboratory data, as an aid in the assessment of hepatic steatosis.
ViTE and LiSA is indicated as a non-invasive aid for the clinical management, diagnosis, and monitoring of patients with liver disease, as part of an overall assessment of 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.
Modes of operation include: B, M, PW Doppler, CWD, Color Doppler, Amplitude Doppler, Tissue Harmonic Imaging, Biopsy guidance, Color M, Contrast imaging (Contrast agent for Liver), ViTE, LiSA and Combined mode: B+M, PW+M, Color+B, Power+B, PW+Color+B, Power+PW+B, iScape View, 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.

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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: **K251601**

1. Submitter

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Date Prepared: December 2, 2025

2. Device Name

Hepatus 7/Hepatus 6/Hepatus 5/Hepatus 7S/Hepatus 6S/Hepatus 5S/Hepatus 7T/Hepatus 6T/Hepatus 5T/Fibrous 7/Fibrous 6/Fibrous 5 Diagnostic Ultrasound System

Classification

Regulatory Class: 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

Hepatus 7 series Diagnostic Ultrasound System is comparable with and substantially equivalent to the predicate device and reference devices listed below. Hepatus 7 (K200643) is the primary predicate device.

Device	Manufacturer	Model	510(k) Number
1. Primary predicate device	Mindray	Hepatus 7	K200643
2. Reference device	Mindray	MX7	K241432
3. Reference device	Mindray	TEX20	K241201
4. Reference device	Mindray	TE7	K203391
5. Reference device	ECHOSENS	FibroScan	K223902

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

Regulation name and code

21 CFR 892.1550 Ultrasonic Pulsed Dopple 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 Hepatus 7/Hepatus 6/Hepatus 5/Hepatus 7S/Hepatus 6S/Hepatus 5S/Hepatus7T/Hepatus 6T/Hepatus 5T/Fibrous 7/Fibrous 6/Fibrous 5 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, PW Doppler, CWD, Color Doppler, Amplitude Doppler, Tissue Harmonic Imaging, Biopsy guidance, Color M, Contrast imaging (Contrast agent for Liver), ViTE, LiSA and Combined mode: B+M, PW+M, Color+B, Power+B, PW+Color+B, Power+PW+B, iScape View, TDI.

The Hepatus 7/Hepatus 6/Hepatus 5/Hepatus 7S/Hepatus 6S/Hepatus 5S/Hepatus7T/Hepatus 6T/Hepatus 5T/Fibrous 7/Fibrous 6/Fibrous 5 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.

Compared to the predicate device Hepatus 7 (K200643), the new features of the subject device are listed in the table below.

Items	New features
Indications for uses	small organ (breast, thyroid, testes), Neonatal Cephalic, Adult Cephalic, musculo-skeletal (conventional), musculo-skeletal (superficial), thoracic/pleural, Cardiac Adult, Cardiac Pediatric.
	Spleen stiffness measurement using ViTE at 100 Hz.

	The liver stiffness measurement by ViTE may aid the physician in determining the likelihood of cirrhosis and may be used, taken in context with other clinical and laboratory data, as an aid in the assessment of liver fibrosis. The coefficient of attenuation measurement by LiSA may be used, taken in context with other clinical and laboratory data, as an aid in the assessment of hepatic steatosis. ViTE and LiSA is indicated as a non-invasive aid for the clinical management, diagnosis, and monitoring of patients with liver disease, as part of an overall assessment of liver.
Probes	LFC5-1s, L9-3s, L15-3RCs, P4-2s
Needle-guided brackets	NGB-034, NGB-011, NGB-043
Functions	iScape View, CW, Tissue Doppler Imaging, Spleen ViTE, Small Parts Package, Pediatrics Package, Nerve Package, Cardiology Package, Emergency&Critical Package

5. Indications for Use:

Hepatus 7/Hepatus 6/Hepatus 5/Hepatus 7S/Hepatus 6S/Hepatus 5S/Hepatus 7T/Hepatus 6T/Hepatus 5T/Fibrous 7/Fibrous 6/Fibrous 5 Diagnostic Ultrasound System is applicable for adults, pregnant women, pediatric patients and neonates. It is intended for use in fetal, abdominal, Pediatric, small organ (breast, thyroid, testes), Neonatal Cephalic, Adult Cephalic, musculo-skeletal (conventional), musculo- skeletal (superficial), thoracic/pleural, Cardiac Adult, Cardiac Pediatric and Peripheral vessel exams.

It is intended to provide 50Hz shear wave speed measurements (ViTE: Visual Transient Elastography) and estimates of tissue stiffness as well as 3.5 MHz ultrasound coefficient of attenuation (LiSA: Liver Ultra-Sound Attenuation) in internal structures of the body.

It is also intended to measure spleen stiffness using ViTE at 100 Hz shear wave frequency.

The liver stiffness measurement by ViTE may aid the physician in determining the likelihood of cirrhosis and may be used, taken in context with other clinical and laboratory data, as an aid in the assessment of liver fibrosis.

The coefficient of attenuation measurement by LiSA may be used, taken in context with other clinical and laboratory data, as an aid in the assessment of hepatic steatosis.

ViTE and LiSA is indicated as a non-invasive aid for the clinical management, diagnosis, and monitoring of patients with liver disease, as part of an overall assessment of 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.

Modes of operation include: B, M, PW Doppler, CWD, Color Doppler, Amplitude Doppler, Tissue Harmonic Imaging, Biopsy guidance, Color M, Contrast imaging (Contrast agent for Liver), ViTE, LiSA and Combined mode: B+M, PW+M, Color+B, Power+B, PW+Color+B, Power+PW+B, iScape View, TDI.

6. Comparison with Predicate Device and Reference devices:

Subject device Hepatus 7/Hepatus 6/Hepatus 5/Hepatus 7S/Hepatus 6S/Hepatus 5S/Hepatus 7T/Hepatus 6T/Hepatus 5T/Fibrous 7/Fibrous 6/Fibrous 5 Diagnostic Ultrasound System is comparable with and substantially equivalent to the primary predicate device and reference devices mentioned in Chapter 3 Predicate Devices with regards to indications for 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 Hepatus 7/Hepatus 6/Hepatus 5/Hepatus 7S/Hepatus 6S/Hepatus 5S/Hepatus 7T/Hepatus 6T/Hepatus 5T/Fibrous 7/Fibrous 6/Fibrous 5 Diagnostic Ultrasound System has the same indications for use as the primary predicate device Hepatus 7 (K200643) except for small organ (breast, thyroid, testes), Neonatal Cephalic, Adult Cephalic, musculo-skeletal (conventional), musculo-skeletal (superficial), thoracic/pleural, Cardiac Adult, Cardiac Pediatric, which are same to the reference device MX7(K241432).

The patient contact materials of the new transducers and new needle-guided brackets of subject device Hepatus 7/Hepatus 6/Hepatus 5/Hepatus 7S/Hepatus 6S/Hepatus 5S/Hepatus 7T/Hepatus 6T/Hepatus 5T/Fibrous 7/Fibrous 6/Fibrous 5 Diagnostic Ultrasound System are the same to the reference devices.

The acoustic power levels of Hepatus 7/Hepatus 6/Hepatus 5/Hepatus 7S/Hepatus 6S/Hepatus 5S/Hepatus 7T/Hepatus 6T/Hepatus 5T/Fibrous 7/Fibrous 6/Fibrous 5 Diagnostic Ultrasound System are below the limits of FDA, which are the same to the primary predicate device Hepatus 7(K200643).

Hepatus 7/Hepatus 6/Hepatus 5/Hepatus 7S/Hepatus 6S/Hepatus 5S/Hepatus 7T/Hepatus 6T/Hepatus 5T/Fibrous 7/Fibrous 6/Fibrous 5 Diagnostic Ultrasound System is designed in compliance with the FDA recognized electrical and physical safety standards, which are the same to the primary predicate device Hepatus 7(K200643).

Hepatus 7/Hepatus 6/Hepatus 5/Hepatus 7S/Hepatus 6S/Hepatus 5S/Hepatus 7T/Hepatus 6T/Hepatus 5T/Fibrous 7/Fibrous 6/Fibrous 5 Diagnostic Ultrasound System has the equivalent features and functions as the primary predicate device. Among these

features, the iScape View, CW, TDI function in proposed Hepatus 7 series are same to the reference device MX7(K241432).

 Hepatus 7/Hepatus 6/Hepatus 5/Hepatus 7S/Hepatus 6S/Hepatus 5S/Hepatus 7T/Hepatus 6T/Hepatus 5T/Fibrous 7/Fibrous 6/Fibrous 5 Diagnostic Ultrasound System has the equivalent features and functions as the primary predicate device. Among these features, the Spleen ViTE supported in proposed Hepatus 7 series is substantially equivalent to the reference device FibroScan (K223902).

 Hepatus 7/Hepatus 6/Hepatus 5/Hepatus 7S/Hepatus 6S/Hepatus 5S/Hepatus 7T/Hepatus 6T/Hepatus 5T/Fibrous 7/Fibrous 6/Fibrous 5 Diagnostic Ultrasound System has the equivalent features and functions as the primary predicate devices. Among these features, the Small Parts Package, Pediatrics Package, Nerve Package, Cardiology Package and Emergency&Critical Package supported in proposed Hepatus 7series are same to the reference device MX7(K241432).

7. Performance data:

Hepatus 7/Hepatus 6/Hepatus 5/Hepatus 7S/Hepatus 6S/Hepatus 5S/Hepatus 7T/Hepatus 6T/Hepatus 5T/Fibrous 7/Fibrous 6/Fibrous 5 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.
- 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 TS 60601-4-2 Edition 1.0 2024-03 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 CONSOLIDATED VERSION, 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 performance data relied on in this premarket notification submission can support the determination of substantial equivalence of the subject device.

8. Summary

Based on the performance data as documented in the study, Hepatus 7/Hepatus 6/Hepatus 5/Hepatus 7S/Hepatus 6S/Hepatus 5S/Hepatus 7T/Hepatus 6T/Hepatus 5T/Fibrous 7/Fibrous 6/Fibrous 5 Diagnostic Ultrasound System was found to have a safety and effectiveness profile that is similar to the primary predicate device.

9.Conclusion:

Indications for use 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 Hepatus 7/Hepatus 6/Hepatus 5/Hepatus 7S/Hepatus 6S/Hepatus 5S/Hepatus 7T/Hepatus 6T/Hepatus 5T/Fibrous 7/Fibrous 6/Fibrous 5 Diagnostic Ultrasound System is substantially equivalent with respect to safety and effectiveness to the primary predicate device.