Shenzhen Mindray Bio-Medical Electronics Co., LTD
℅ Jiang Xiaoyong
Engineer of Technical Regulation
Mindray Building, Keji 12th Road South,
Hi-tech Industrial Park
Nanshan, Shenzhen, 518057
P.R. CHINA

July 24, 2020

Re: K200643
Trade/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
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: May 23, 2020
Received: June 12, 2020

Dear Jiang Xiaoyong:

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)*

K200643

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 and Peripheral vessel exams.
It is intended to provide 50 Hz 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.
The ViTE and stiffness, and LiSA may be used as an aid to diagnosis and monitoring of adult patients with liver disease, as part of an overall assessment of liver.
The ViTE and stiffness may be used as an aid to clinical management of pediatric patients with liver disease.
The clinical applications include:Fetal, Abdominal, Pediatric and Peripheral vessel.

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, 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.

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.

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.

The assigned 510(k) number is: K200643

1. Submitter:

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Contact Person:
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Nanshan, Shenzhen, 518057, P. R. China

Date Prepared: March 2, 2020

2. Device Name: Hepatus 7/Hepatus 6/Hepatus 5/Hepatus 7S/Hepatus 6S/Hepatus 5S/Hepatus7T/Hepatus 6T/Hepatus 5T/Fibrous 7/Fibrous 6/Fibrous 5Diagnostic 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:

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 a general purpose, mobile, software controlled, ultrasound diagnostic system. Its function is to acquire and display ultrasound images in B-mode, M-mode, PW-mode, Color-mode, Color M-mode, Power/Dirpower mode, THI, Biopsy Guidance, ViTE, Contrast imaging or the combined mode (i.e. B/M-Mode).

This system is a Track 3 device that employs an array of probes that include convex array and phased array.

4. Indication 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 and Peripheral vessel exams.

It is intended to provide 50 Hz 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.

The ViTE and stiffness, and LiSA may be used as an aid to diagnosis and monitoring of adult patients with liver disease, as part of an overall assessment of liver.

The ViTE and stiffness may be used as an aid to clinical management of pediatric patients with liver disease.

The clinical applications include: Fetal, Abdominal, Pediatric and Peripheral vessel.

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, 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.

6. Comparison with Predicate Devices:

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 these predicate devices:

Predicate Device	Manufacturer	Model	510(k) Control Number
1. Primary predicate device	Mindray	TE7/TE5	K180912
2. Reference device	Mindray	M9	K171034
3. Reference device	ECHOSENS	FIBROSCAN 502 Touch	K123806
4. Reference device	ECHOSENS	FIBROSCAN 502 Touch	K150949

In addition to ViTE technology and LiSA function, 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 employs the same technology as the primary predicate device. The subject device and the primary predicate device transmit ultrasonic energy into patients, then perform post processing of received echoes to generate onscreen display of anatomic structures and fluid flow within the body. They also allow for specialized measurements of structures and flow, and calculations.

The ViTE technology used in the subject device and the VCTE technology used in the reference device (K123806) are both based on transient elastography. This technology is that a mechanical vibrator produces low-amplitude elastic waves that travel through the skin and intercostal space into the liver. The subject device and the reference device (K123806) both use ultrasound to track the shear wave and to measure shear wave speed,

which is correlated with the elasticity of the liver. Besides, the subject device and the reference device (K123806) display the same physical variable(shear wave speed).
Also, the subject device and the reference device (K123806) have same indications for use, which is intended to provide 50Hz shear wave speed measurements and estimates of tissue stiffness. And the shear wave speed and stiffness of subject device and reference device (K123806) both may be used as an aid to clinical management of adult patients and pediatric patients with liver disease.
Therefore ViTE technology of the subject device and ViTE technology of the reference device (K123806) are substantially equivalent.

LiSA function is designed to provide an estimation of the total aforementioned ultrasonic wave attenuation(forward and return paths) at 3.5MHz, measured concomitantly with tissue stiffness , which is identical to the controlled attenuation parameter (CAP, cleared by K150949). The soft tissue attenuation application of the subject device is substantially equivalent to the attenuation applications in the reference device (K150949).
Also, the subject device and the reference device (K150949) have same indications for use, which is indicated for noninvasive measurement in the liver of 3.5MHz ultrasound coefficient of attenuation. And the ultrasound coefficient of attenuation of subject device and reference device (K150949) both may be used as an aid to clinical management of adult patients with liver disease.
Therefore LiSA function of the subject device and CAP function of the reference device (K150949) are substantially equivalent.

- 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 has the similar intended uses with the predicated device TE7/TE5(K180912).
- The materials of C5-1s probe and Needle-guided bracket(NGB-022) 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 are the same to the predicate device TE7/TE5(K180912).
- 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 are below the limits of FDA, which is the same as the predicated device TE7/TE5(K180912).

- Hepatus 7/Hepatus 6/Hepatus 5/Hepatus 7S/Hepatus 6S/Hepatus 5S/Hepatus 7T/Hepatus 6T/Hepatus 5T/Fibrous 7/Fibrous 6/Fibrous 5 is designed in compliance with the FDA recognized electrical and physical safety standards, which are the same as the predicated device TE7/TE5(K180912).

7. Non-clinical Tests:

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 has been found to conform with applicable medical safety standards.

Non-clinical tests relied on in this premarket notification submission for a determination of substantial equivalence include testing showing compliance with 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 Second edition 2007-03-01, medical devices - application of risk management to medical devices.
- NEMA UD 2-2004 (R2009), acoustic output measurement standard for diagnostic

ultrasound equipment revision 3.

- AAMI / ANSI / ISO 10993-1:2009/(R)2013, 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

8. Clinical Tests:

Not Applicable.

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 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 devices currently cleared for market.