June 9, 2023

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
℅ Tang Jing
Engineer of Technical Regulation
Keji 12th Road South, Hi-tech Industrial Park
Shenzhen, Guangdong 518057
CHINA

Re: K230768
Trade/Device Name: M9/M9CV/M9T/M8 Elite/M10/M10CV/Crius M10/M11/M11CV/Crius M11/Operus M11/M9 Premium 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: March 9, 2023
Received: March 20, 2023

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 (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,

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)*

K230768

Device Name

M9/M9CV/M9T/M8 Elite/M10/M10CV/Crius M10/M11/M11CV/Crius M11 /Operus M11/M9 Premium Diagnostic Ultrasound System

Indications for Use *(Describe)*

The M9/M9CV/M9T/M8 Elite/M10/M10CV/Crius M10/M11/M11CV/Crius M11 /Operus M11/M9 Premium Diagnostic Ultrasound System is applicable for adults, pregnant women, pediatric patients and neonates.

It is intended for use in fetal, abdominal, Intra-operative, Laparoscopic, pediatric, small organ(breast, thyroid, testes), neonatal and adult cephalic, trans-rectal, trans-vaginal, musculo-skeletal(conventional, superficial), adult and pediatric cardiac, trans-esoph.(Cardiac), peripheral vessel 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 tc 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, iScape, TDI, Color M, Elastography, Contrast imaging (Contrast agent for LVO), Smart 3D, 4D(Real-time 3D), 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.

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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: K230768

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:
Tang Jing
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: May 26, 2023

2. Device Name: M9/M9CV/M9T/M8 Elite/M10/M10CV/Crius M10/M11/M11CV/ Crius M11/Operus M11/M9 Premium 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: M9/M9CV/M9T/M8 Elite/M10/M10CV/Crius M10/M11/M11CV/ Crius M11/Operus M11/M9 Premium Diagnostic Ultrasound System (cleared in K210416).

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 M9/M9CV/M9T/M8 Elite/M10/M10CV/Crius M10/M11/M11CV/Crius M11/Operus M11/M9 Premium Diagnostic Ultrasound System is a general purpose, portable, software controlled, ultrasonic diagnostic system. Its function is to acquire and display ultrasound data in 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, iScape, TDI, Color M, Elastography, Contrast imaging (Contrast agent for LVO), Smart 3D, 4D(Real-time 3D), Contrast imaging (Contrast agent for Liver).

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

4. Intended Use:

The Diagnostic Ultrasound System is applicable for adults, pregnant women, pediatric patients and neonates. It is intended for use in fetal, abdominal, Intra-operative, Laparoscopic, pediatric, small organ(breast, thyroid, testes), neonatal and adult cephalic, trans-rectal, trans-vaginal, musculo-skeletal(conventional, superficial), adult and pediatric cardiac, trans-esoph.(Cardiac), peripheral vessel 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, CWD, Color Doppler, Amplitude Doppler, Combined mode(B+M, PW+B, Color+B, Power+B, PW+Color+B, Power+PW+B), Tissue Harmonic Imaging, iScape, TDI, Color M, Elastography, Contrast imaging (Contrast agent for LVO), Smart 3D, 4D(Real-time 3D), Contrast imaging (Contrast agent for Liver).

5. Summary of Modifications

Newly Added Transducers: P8-2s

5.1 An overall description of the transducer P8-2s design

5.1.1 Illustration of the P8-2s

Fig.1 Transducer picture

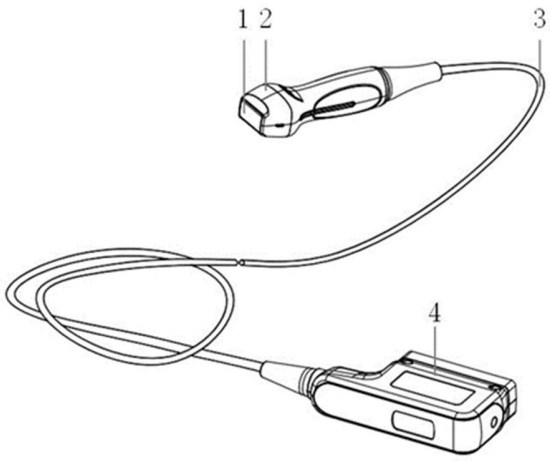

Fig.2 Overview

No.	Item	Description
1.	Probe head	Converts the electrical signal into an ultrasonic signal, focusing the sound beams in a given direction; meanwhile, it receives the reflected ultrasonic signal and converts it into an electrical signal for transmission over the cable. The lens on the surface is the acoustic lens. Apply ultrasound gel on the acoustic lens for correct operation.
2.	Probe shell	Fix the probe head and provide the gripping position.
3.	Probe cable	Transmits electrical signals between the probe body and connector.
4.	Probe connector	Connects the probe and cable to the ultrasonic diagnostic system.

5.1.2 Major parameters of the P8-2s is listed in the table below

Transducer	Nominal frequency (MHz)	Geometrical shape	Array elements	Radius /Width (mm)	Distance between adjacent elements (mm)	Axis size (mm)	Maximum number of active elements
P8-2s	5MHz	Phased	96	/	0.16	8	96

5.1.3 Indication(s) for use and Mode of operation of the P8-2s

Transducer	P8-2s
Indication(s) for use	Abdominal, Pediatric, Neonatal Cephalic, Adult Cephalic, Musculo-skeletal (Conventional), Cardiac Adult, Cardiac Pediatric
Modes of operation	B, M, PWD, CWD, Color Doppler, Amplitude Doppler, Combined Modes, Tissue Harmonic Imaging, iScape, Color M, Smart 3D, TDI

5.2 Materials of the P8-2s

Transducer		Materials	Contact type
P8-2s	Probe shell	Valox 3706（colour number：MR-DS193-S）	Contact the normal skin, short-term contact
	Acoustic lens	MLG-34-G/MLG-34-N	
	Mucilage glue	RTV162	
		RTV167	

5.3 Energy sources of the P8-2s

Energy source	acoustic output power
Is the acoustic output below Ispta.3 = 720mW/cm2 and either MI=1.9 or Isppa.3 =190W/cm2?	yes
Acoustic output is measured and recorded according to the procedures in 510(k) guidance?	yes

6. Comparison with Predicate Devices:

The M9/M9CV/M9T/M8 Elite/M10/M10CV/Crius M10/M11/M11CV/Crius M11 /Operus M11/M9 Premium Diagnostic Ultrasound System is comparable with and substantially equivalent to the predicate device:

Predicate Device	Manufacturer	Model	510(k) Control Number
1. Primary predicate device	Mindray	M9	K210416

The M9/M9CV/M9T/M8 Elite/M10/M10CV/Crius M10/M11/M11CV/Crius M11/Operus M11/M9 Premium Diagnostic Ultrasound System 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 device. 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 M9 (K210416) have identical imaging modes.
- The subject device has similar probes as the predicate M9 (K210416) however the proposed subject device has the P8-2s, but it can be substantial equivalent with P7-3s(K210416).
- The acoustic power levels of subject device are below the limits of FDA, which is the same as the predicated device M9 (K210416)
- The subject device is designed in compliance with the FDA recognized electrical and physical safety standard, which is the same as the predicated device M9 (K210416).

7. Non-clinical Tests:

The M9/M9CV/M9T/M8 Elite/M10/M10CV/Crius M10/M11/M11CV/Crius M11 /Operus M11/M9 Premium Diagnostic Ultrasound System has been evaluated for acoustic output, biocompatibility, cleaning, disinfection and sterilization 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.

8. Clinical Studies

Not applicable. The subject of this submission, M9/M9CV/M9T/M8 Elite/M10 /M10CV/Crius M10/M11/M11CV/Crius M11/Operus M11/M9 Premium 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 M9/M9CV/M9T/M8 Elite/M10/M10CV/Crius M10/M11/M11CV/Crius M11/Operus M11/M9 Premium Diagnostic Ultrasound System is substantially equivalent with respect to safety and effectiveness to devices currently cleared for market.