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

June 10, 2021

Re: K210699
Trade/Device Name: Resona I9, Resona I9 Exp, Resona I9S, Resona I9T, Resona I9 Easi, Resona I9 Nasa, Resona IV, Imagyn I9, Imagyn I9S, Imagyn I9 Easi, Nuewa I9, Nuewa I9S, Nuewa I9T, Nuewa I9 Exp, Nuewa I9 Easi, Anesus I9, Anesus I9 Easi, Eagus I9 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 24, 2021
Received: May 27, 2021

Dear Hao Yixuan:

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K210699

Device Name

Resona I9/Resona I9 Exp/Resona I9S/Resona I9T/Resona I9 Easi/Resona I9 Nasa/Resona IV/Imagyn I9/Imagyn I9S/Imagyn I9 Easi/ Nuewa I9/Nuewa I9S/ Nuewa I9T/Nuewa I9 Exp/Nuewa I9 Easi/Anesus I9/Anesus I9 Easi/Eagus I9 Diagnostic Ultrasound System

Indications for Use *(Describe)*

Resona I9/Resona I9 Exp/Resona I9S/Resona I9T/Resona I9 Easi/Resona I9 Nasa/Resona IV/Imagyn I9/Imagyn I9S/ Imagyn I9 Easi/Nuewa I9/Nuewa I9S/ Nuewa I9T/Nuewa I9 Exp/Nuewa I9 Easi/Anesus I9/Anesus I9 Easi/Eagus I9 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 and adult cephalic, trans-rectal, trans-vaginal, musculo-skeletal (conventional, superficial), adult and pediatric cardiac, trans-esoph. (Cardiac), peripheral vessel, urology and Thoracic/Pleural exams.

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, 4D(Real-time 3D), iScape View, TDI, Color M, Strain Elastography, Contrast imaging (Contrast agent for LVO), V Flow, STE, STQ, 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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010-1

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: K210699

1. Submitter

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Contact Person

Hao Yixuan
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: February 28, 2021

2. Device Name

Resona I9, Resona I9 Exp, Resona I9S, Resona I9T, Resona I9 Easi, Resona I9 Nasa, Resona IV, Imagyn I9, Imagyn I9S, Imagyn I9 Easi, Nuewa I9, Nuewa I9S, Nuewa I9T, Nuewa I9 Exp, Nuewa I9 Easi, Anesus I9, Anesus I9 Easi, Eagus I9 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. Predicate devices

Resona I9 series Diagnostic Ultrasound System is comparable with and substantially equivalent to the predicate devices listed below. Resona 7 is the main predicate devices.

Device	Manufacturer	Model	Device Class	Product Code	510K Number
1. Main predicate device	Mindray	Resona 7	II	IYN, IYO, ITX	K171233
2. Reference device	Mindray	DC-80	II	IYN, IYO, ITX, LLZ	K192152
3. Reference device	Mindray	MX7	II	IYN, IYO, ITX	K200001
4. Reference device	Mindray	ZS3	II	IYN, IYO, ITX	K192410
5. Reference device	Samsung	RS85	II	IYN, IYO, ITX	K192903
6. Reference device	SuperSonic	Aixplorer	II	IYN, IYO, ITX	K173021
7. Reference device	GE	LOGIQ E9	II	IYN, IYO, ITX	K163077
8. Reference device	GE	VOLUS ON E8	II	IYN, IYO, ITX	K181985

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

Regulation name and code

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)

21 CFR 892.2050 Picture Archiving and Communications System (LLZ)

4. Device Description:

The Resona I9, Resona I9 Exp, Resona I9S, Resona I9T, Resona I9 Easi, Resona I9 Nasa, Resona IV, Imagyn I9, Imagyn I9S, Imagyn I9 Easi, Nuewa I9, Nuewa I9S, Nuewa I9T, Nuewa I9 Exp, Nuewa I9 Easi, Anesus I9, Anesus I9 Easi, Eagus I9 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, 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, 4D(Real-time 3D), iScape View, TDI, Color M, Strain Elastography, Contrast imaging (Contrast agent for LVO), V Flow, STE, STQ, Contrast imaging (Contrast agent for Liver).

The Resona I9, Resona I9 Exp, Resona I9S, Resona I9T, Resona I9 Easi, Resona I9 Nasa, Resona IV, Imagyn I9, Imagyn I9S, Imagyn I9 Easi, Nuewa I9, Nuewa I9S, Nuewa I9T, Nuewa I9 Exp, Nuewa I9 Easi, Anesus I9, Anesus I9 Easi, Eagus I9 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.

5. Intended Use:

Resona I9/Resona I9 Exp/Resona I9S/Resona I9T/Resona I9 Easi/Resona I9 Nasa/ Resona IV/Imagyn I9/Imagyn I9S/Imagyn I9 Easi/Nuewa I9/Nuewa I9S/Nuewa I9T/Nuewa I9 Exp/Nuewa I9 Easi/Anesus I9/Anesus I9 Easi/Eagus I9 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 and adult cephalic, trans-rectal, trans-vaginal, musculo-skeletal (conventional, superficial), adult and pediatric cardiac, trans-esoph. (Cardiac), peripheral vessel, urology and Thoracic/Pleural exams.

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, 4D(Real-time 3D), iScape View, TDI, Color M, Strain Elastography, Contrast imaging (Contrast agent for LVO), V Flow, STE, STQ, Contrast imaging (Contrast agent for Liver).

6. Comparison with Predicate Devices:

Subject device Resona I9, Resona I9 Exp, Resona I9S, Resona I9T, Resona I9 Easi, Resona I9 Nasa, Resona IV, Imagyn I9, Imagyn I9S, Imagyn I9 Easi, Nuewa I9, Nuewa I9S, Nuewa I9T, Nuewa I9 Exp, Nuewa I9 Easi, Anesus I9, Anesus I9 Easi, Eagus I9 Diagnostic Ultrasound System is comparable with and substantially equivalent to these predicate devices mentioned in *3. Predicate* Devices with regards to intended 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 Resona I9, Resona I9 Exp, Resona I9S, Resona I9T, Resona I9 Easi, Resona I9 Nasa, Resona IV, Imagyn I9, Imagyn I9S, Imagyn I9 Easi, Nuewa I9, Nuewa I9S, Nuewa I9T, Nuewa I9 Exp, Nuewa I9 Easi, Anesus I9, Anesus I9 Easi, Eagus I9 Diagnostic Ultrasound System has the same intended uses as the predicated device Resona 7 (K171233) except the thoracic/pleural exam, which has been cleared on predicate device MX7(K200001) and the imaging modes as the predicated devices.

- The patient contact materials of the transducers and needle-guided brackets of subject device Resona I9, Resona I9 Exp, Resona I9S, Resona I9T, Resona I9 Easi, Resona I9 Nasa, Resona IV, Imagyn I9, Imagyn I9S, Imagyn I9 Easi, Nuewa I9, Nuewa I9S, Nuewa I9T, Nuewa I9 Exp, Nuewa I9 Easi, Anesus I9, Anesus I9 Easi, Eagus I9 Diagnostic Ultrasound System are the same to the predicate devices or tested under ISO 10993-1.
- The acoustic power levels of Resona I9, Resona I9 Exp, Resona I9S, Resona I9T, Resona I9 Easi, Resona I9 Nasa, Resona IV, Imagyn I9, Imagyn I9S, Imagyn I9 Easi, Nuewa I9, Nuewa I9S, Nuewa I9T, Nuewa I9 Exp, Nuewa I9 Easi, Anesus I9, Anesus I9 Easi, Eagus I9 are below the limits of FDA, which are the same as the predicated device Resona 7 (K171233).
- Resona I9, Resona I9 Exp, Resona I9S, Resona I9T, Resona I9 Easi, Resona I9 Nasa, Resona IV, Imagyn I9, Imagyn I9S, Imagyn I9 Easi, Nuewa I9, Nuewa I9S, Nuewa I9T, Nuewa I9 Exp, Nuewa I9 Easi, Anesus I9, Anesus I9 Easi, Eagus I9 is designed in compliance with the FDA recognized electrical and physical safety standards, which are the same as the predicated device Resona 7 (K171233).
- The Resona I9, Resona I9 Exp, Resona I9S, Resona I9T, Resona I9 Easi, Resona I9 Nasa, Resona IV, Imagyn I9, Imagyn I9S, Imagyn I9 Easi, Nuewa I9, Nuewa I9S, Nuewa I9T, Nuewa I9 Exp, Nuewa I9 Easi, Anesus I9, Anesus I9 Easi, Eagus I9 has the equivalent features and functions as the predicated devices.

For the differences compared to the predicate devices:

- The Resona I9, Resona I9 Exp, Resona I9S, Resona I9T, Resona I9 Easi, Resona I9 Nasa, Resona IV, Imagyn I9, Imagyn I9S, Imagyn I9 Easi, Nuewa I9, Nuewa I9S, Nuewa I9T, Nuewa I9 Exp, Nuewa I9 Easi, Anesus I9, Anesus I9 Easi, Eagus I9 **introduces new software and hardware options** which in the below table that used as improvements or enhancement based on the cleared functions to facilitate users, no new intended use are added and all of them have passed the related tests, no clinical risks have been recognized nor introduced.

High frame rate STE	High frame rate STE function is used to improve the frame rate (FR) for STE. High frame rate STE is a High frame rate mode of STE
Smart Scene 3D	In 3D/4D acquisition preparation status, this feature can adjust ROI size and position automatically and activate appropriate render modes according to the recognized anatomical structure of some organs.
CPP	Measures the pixel proportion of blood flow signal in the region of interest under Color or Power mode. The feature is not supported under TDI mode.

DICOM Small Parts SR	DICOM basic unit installed first. Purpose: The ultrasound system transfers the measurements obtained from Small Parts studies to storage devices.
Battery assembly	There are two kinds of standby battery assemblies, 4 sets and 8 sets of batteries.
iClear^{+} Dongle	This optional hardware should be installed to realize the iClear^{+} function
Probe Adapter PCM-ES01 and PCM-US01	The probe adapter is used for probe-unit interface conversion. PCM-US01 Probe Adapter is used for probes with U-type socket to connect to the main unit with S-type socket accepted interface. The P7-3TU or SP5-1U probe should be configured. PCM-ES01 Probe Adapter is used for probes with E-type socket to connect to the main unit with S-type socket accepted interface. The SD8-1E, P7-3TE, SC6-1E, or SP5-1E probe should be configured.
Magnetic navigation controller box	Used for carrying the magnetic navigation controller.

7. Non-clinical Tests:

Resona I9, Resona I9 Exp, Resona I9S, Resona I9T, Resona I9 Easi, Resona I9 Nasa, Resona IV, Imagyn I9, Imagyn I9S, Imagyn I9 Easi, Nuewa I9, Nuewa I9S, Nuewa I9T, Nuewa I9 Exp, Nuewa I9 Easi, Anesus I9, Anesus I9 Easi, Eagus I9 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.
- 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 disturbances - Requirements and tests
- 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.

- 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 Second edition 2007-03-01, 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, medical device software - software life cycle processes.
- IEC 62366-1 Edition 1.0 2015-02 Medical devices - Part 1: Application of usability engineering to medical devices [Including CORRIGENDUM 1 (2016)].

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, Resona I9, Resona I9 Exp, Resona I9S, Resona I9T, Resona I9 Easi, Resona I9 Nasa, Resona IV, Imagyn I9, Imagyn I9S, Imagyn I9 Easi, Nuewa I9, Nuewa I9S, Nuewa I9T, Nuewa I9 Exp, Nuewa I9 Easi, Anesus I9, Anesus I9 Easi, Eagus I9 Diagnostic Ultrasound System, does not require clinical studies to support substantial equivalence.

9. Summary

Based on the performance data as documented in the study, the Resona I9, Resona I9 Exp, Resona I9S, Resona I9T, Resona I9 Easi, Resona I9 Nasa, Resona IV, Imagyn I9, Imagyn I9S, Imagyn I9 Easi, Nuewa I9, Nuewa I9S, Nuewa I9T, Nuewa I9 Exp, Nuewa I9 Easi, Anesus I9, Anesus I9 Easi, Eagus I9 Diagnostic Ultrasound system was found to have a safety and effectiveness profile that is similar to the predicate device.

10.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 Resona I9, Resona I9 Exp, Resona I9S, Resona I9T, Resona I9 Easi, Resona I9 Nasa, Resona IV, Imagyn I9, Imagyn I9S,

Imagyn I9 Easi, Nuewa I9, Nuewa I9S, Nuewa I9T, Nuewa I9 Exp, Nuewa I9 Easi, Anesus I9, Anesus I9 Easi, Eagus I9 Diagnostic Ultrasound System is substantially equivalent with respect to safety and effectiveness to its primary predicate device Resona 7.