May 19, 2025

Shenzhen Mindray Bio-medical Electronics Co., Ltd.
Wei Zhang
Technical manager, Technical Regulation Department
Mindray Building, Keji 12th Road South,
Hi-tech Industrial Park, Nanshan
Shenzhen, Guangdong 518057
China

Re: K250020
Trade/Device Name: Diagnostic Ultrasound System (Recho R9W); Diagnostic Ultrasound System (Recho R9); Diagnostic Ultrasound System (Recho R9 Pro); Diagnostic Ultrasound System (Recho R9 Exp); Diagnostic Ultrasound System (Recho R9S); Diagnostic Ultrasound System (Recho R9T); Diagnostic Ultrasound System (Crius R9 CV); Diagnostic Ultrasound System (Anesus R9 CV); Diagnostic Ultrasound System (Recho R9 Super); Diagnostic Ultrasound System (Recho R9 Lumi); Diagnostic Ultrasound System (Recho R CV); Diagnostic Ultrasound System (Recho R CVx)
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic Pulsed Doppler Imaging System
Regulatory Class: Class II
Product Code: IYN, IYO, ITX, LLZ
Dated: April 21, 2025
Received: April 21, 2025

Dear Wei Zhang:

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,

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K250020

Device Name

Diagnostic Ultrasound System (Recho R9W);
Diagnostic Ultrasound System (Recho R9);
Diagnostic Ultrasound System (Recho R9 Pro);
Diagnostic Ultrasound System (Recho R9 Exp);
Diagnostic Ultrasound System (Recho R9S);
Diagnostic Ultrasound System (Recho R9T);
Diagnostic Ultrasound System (Crius R9 CV);
Diagnostic Ultrasound System (Anesus R9 CV);
Diagnostic Ultrasound System (Recho R9 Super);
Diagnostic Ultrasound System (Recho R9 Lumi);
Diagnostic Ultrasound System (Recho R CV);
Diagnostic Ultrasound System (Recho R CVx)

Indications for Use *(Describe)*

Recho R9W/Recho R9/Recho R9 Pro/Recho R9 Exp/Recho R9S/Recho R9T/Crius R9 CV/Anesus R9 CV/Recho R9 Super/Recho R9 Lumi/Recho R CV/Recho R CVx 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-rectal, trans-vaginal, musculo-skeletal(conventional, superficial), thoracic/pleural, 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, Smart 3D, 4D, Matrix 4D, 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.

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: K250020

1. Submitter

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Date Prepared: December 27, 2024

2. Device Name

Recho R9W, Recho R9, Recho R9 Pro, Recho R9 Exp, Recho R9S, Recho R9T, Crius R9 CV, Anesus R9 CV, Recho R9 Super, Recho R9 Lumi, Recho R CV, Recho R CVx 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

Recho R9W series Diagnostic Ultrasound System is comparable with and substantially equivalent to the predicate devices listed below. Recho R9W is the main predicate devices.

Device	Manufacturer	Model	Device Class	Product Code	510K Number
1. Main predicate device	Mindray	Resona R9	II	IYN, IYO, ITX	K222928
2. Reference device	Mindray	TEX20	II	IYN, IYO, ITX	K220242
3. Reference device	Philips	EPIQ 7	II	IYN, IYO, ITX	K182857
4. Reference device	Philips	QLab	II	LLZ	K190913 K171314
5.Reference device	Mindray	Resona I9	II	IYN, IYO, ITX	K240115
6.Reference device	Mindray	Resona A10S	II	IYN, IYO, ITX	K242231

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 Recho R9W, Recho R9, Recho R9 Pro, Recho R9 Exp, Recho R9S, Recho R9T, Crius R9 CV, Anesus R9 CV, Recho R9 Super, Recho R9 Lumi, Recho R CV, Recho R CVx 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, Smart 3D, 4D, Matrix 4D, iScape View, TDI, Color M, Strain Elastography, Contrast imaging (Contrast agent for LVO), V Flow, STE, STQ, Contrast imaging (Contrast agent for Liver).

The Recho R9W, Recho R9, Recho R9 Pro, Recho R9 Exp, Recho R9S, Recho R9T, Crius R9 CV, Anesus R9 CV, Recho R9 Super, Recho R9 Lumi, Recho R CV, Recho R CVx 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:

Recho R9W, Recho R9, Recho R9 Pro, Recho R9 Exp, Recho R9S, Recho R9T, Crius R9 CV, Anesus R9 CV, Recho R9 Super, Recho R9 Lumi, Recho R CV, Recho R CVx 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-rectal, trans-vaginal, musculo-skeletal(conventional, superficial), thoracic/pleural, 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, Smart 3D, 4D, Matrix 4D, 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 Recho R9W, Recho R9, Recho R9 Pro, Recho R9 Exp, Recho R9S, Recho R9T, Crius R9 CV, Anesus R9 CV, Recho R9 Super, Recho R9 Lumi, Recho R CV, Recho R CVx 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 Recho R9W, Recho R9, Recho R9 Pro, Recho R9 Exp, Recho R9S, Recho R9T, Crius R9 CV, Anesus R9 CV, Recho R9 Super, Recho R9 Lumi, Recho R CV, Recho R CVx Diagnostic Ultrasound System has the same intended uses as the predicated device Resona R9 (K222928) except thoracic/pleural application and Matrix 4D function. At the same time, thoracic/pleural application have been cleared in predicate device TEX20

(K220242), and the Matrix 4D has been cleared in predicate device EPIQ 7 (K182857).

- The patient contact materials of the transducers and needle-guided brackets of subject device Recho R9W, Recho R9, Recho R9 Pro, Recho R9 Exp, Recho R9S, Recho R9T, Crius R9 CV, Anesus R9 CV, Recho R9 Super, Recho R9 Lumi, Recho R CV, Recho R CVx Diagnostic Ultrasound System are the same to the predicate devices or tested under ISO 10993-1.
- The acoustic power levels of Recho R9W, Recho R9, Recho R9 Pro, Recho R9 Exp, Recho R9S, Recho R9T, Crius R9 CV, Anesus R9 CV, Recho R9 Super, Recho R9 Lumi, Recho R CV, Recho R CVx Diagnostic Ultrasound System are below the limits of FDA, which are the same as the predicated devices Resona R9 (K222928) and EPIQ 7 (K182857).
- Recho R9W, Recho R9, Recho R9 Pro, Recho R9 Exp, Recho R9S, Recho R9T, Crius R9 CV, Anesus R9 CV, Recho R9 Super, Recho R9 Lumi, Recho R CV, Recho R CVx Diagnostic Ultrasound System is designed in compliance with the FDA recognized electrical and physical safety standards, which are the same as the predicated device Resona R9 (K222928).
- Recho R9W, Recho R9, Recho R9 Pro, Recho R9 Exp, Recho R9S, Recho R9T, Crius R9 CV, Anesus R9 CV, Recho R9 Super, Recho R9 Lumi, Recho R CV, Recho R CVx Diagnostic Ultrasound System has the equivalent features and functions as the predicated devices. Among these features, the Auto Strain LV, Auto Strain RV, Auto VQ LA and X-Vue supported in proposed Recho R9W series have been cleared in predicate device QLab (K190913) and (K171314). and Matrix 4D Function supported in proposed Recho R9W series have been cleared in predicate device EPIQ7(K182857).

For the differences compared to the predicate devices:

- The subject device introduces new options, which in the below table that either the improvements or enhancement based on the cleared functions to facilitate user, no intended uses are added and passed the related tests, no clinical risks introduced.

Subject Device	Function explanation
Quick View	Quick View Before entering the Matrix 4D Function, you can quickly select views to capture volume data of commonly-used cardiac planes.

7. Non-clinical Tests:

Recho R9W, Recho R9, Recho R9 Pro, Recho R9 Exp, Recho R9S, Recho R9T, Crius

R9 CV, Anesus R9 CV, Recho R9 Super, Recho R9 Lumi, Recho R CV, Recho R CVx 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 TR 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, 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 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, Recho R9W, Recho R9, Recho R9 Pro, Recho R9 Exp, Recho R9S, Recho R9T, Crius R9 CV, Anesus R9 CV, Recho R9 Super, Recho R9 Lumi, Recho R CV, Recho R CVx Diagnostic Ultrasound System, does not require clinical studies to support substantial equivalence.

9. Summary

Based on the performance data as documented in the study, Recho R9W, Recho R9, Recho R9 Pro, Recho R9 Exp, Recho R9S, Recho R9T, Crius R9 CV, Anesus R9 CV, Recho R9 Super, Recho R9 Lumi, Recho R CV, Recho R CVx 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 Recho R9W, Recho R9, Recho R9 Pro, Recho R9 Exp, Recho R9S, Recho R9T, Crius R9 CV, Anesus R9 CV, Recho R9 Super, Recho R9 Lumi, Recho R CV, Recho R CVx Diagnostic Ultrasound System is substantially equivalent with respect to safety and effectiveness to the predicate devices.