February 7, 2023

Shenzhen Mindray Bio-Medical Electronics Co., LTD
℅ Zhang Wei
Engineer of Technical Regulation
Mindray Bldg.
Keji 12th Road South, Hi-tech Industrial Park
Shenzhen, Guangdong 518057
CHINA

Re: K222928
Trade/Device Name: Resona R9/ Resona R9 Exp/ Resona R9 Pro/ Resona R9S/ Nuewa R9/ Nuewa R9 Exp/ Nuewa R9 Pro/ Nuewa R9S/ Resona 7/ Resona 7CV/Resona 7EXP/Resona 7S/ Resona 7OB/ Resona 7PRO/Imagyn 7/ Resona Y/Resona R9W/Resona R7W Nuewa R9W/Nuewa R7W 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: December 15, 2022
Received: January 3, 2023

Dear Zhang Wei:

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)*
K222928

Device Name
Resona R9/Resona R9 Exp/Resona R9 Pro/Resona R9S/Nuewa R9/Nuewa R9 Exp/Nuewa R9 Pro/Nuewa R9S/Resona 7/Resona 7CV/Resona 7EXP/Resona 7S/Resona 7OB/Resona 7PRO/Imagyn 7/Resona Y / Resona R9W/ Resona R7W/ Nuewa R9W/ Nuewa R7W Diagnostic Ultrasound System

Indications for Use *(Describe)*
Resona R9/Resona R9 Exp/Resona R9 Pro/Resona R9S/Nuewa R9/Nuewa R9 Exp/Nuewa R9 Pro/Nuewa R9S/Resona 7/ Resona 7CV/Resona 7EXP/Resona 7S/Resona 7OB/Resona 7PRO/Imagyn 7/Resona Y / Resona R9W/ Resona R7W/ Nuewa R9W/ Nuewa R7W Diagnostic Ultrasound System is applicable for adults, pregnant women, pediatric patients and neonates. It is intended for use in fetal, abdominal, Intra-operative, 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 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(Pulse wave Doppler), CWD(Continuous wave Doppler), 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(Real-time 3D), iScape View, TDI(Tissue Doppler Imaging), Color M, Strain Elastography, Contrast imaging (Contrast agent for LVO(Left Ventricular Opacification)), V Flow(Vector Flow), STE(Sound Touch Elastography), STQ(Sound Touch Quantification), 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.**

# 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: K222928

## 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 6566
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**Contact Person:**
Zhang Wei
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Nanshan, Shenzhen, 518057, P. R. China

**Date Prepared:** August 30, 2022

## 2. Device Name:

Resona R9, Resona R9 Exp, Resona R9 Pro, Resona R9S, Nuewa R9, Nuewa R9 Exp, Nuewa R9 Pro, Nuewa R9S, Resona 7, Resona 7CV, Resona 7EXP, Resona 7S, Resona 7OB, Resona 7PRO, Imagyn 7, Resona Y, Resona R9W, Resona R7W, Nuewa R9W, Nuewa R7W 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 R9 series Diagnostic Ultrasound System is substantially equivalent in its

technologies and functionality to Resona R9（K202785） Diagnostic Ultrasound System (predicate devices) that are already cleared by FDA, and they are listed below. Resona R9 is the main predicate devices.

| Device | Manufacturer | Model | Device Class | Product Code | 510(k) Number |
|---|---|---|---|---|---|
| 1. Main predicate device | Mindray | Resona R9 | II | IYN, IYO, ITX | K202785 |
| 2. Reference device | Mindray | Resona I9 | II | IYN, IYO, ITX， | K210699 |
| 3. Reference device | GE | Voluson E10 | II | IYN, IYO, ITX | K192159 |
| 4. Reference device | GE | LOGIQ E10 | II | IYN, IYO, ITX | K211488 |
| 5. Reference device | Mindray | Hepatus 7 | II | IYN, IYO, ITX | K200643 |
| 6. Reference device | MylabTwice | 6200 | II | IYN, IYO, ITX | K100931 |
| 7. Reference device | Philips | EPIQ | II | IYN, IYO, ITX | K212704 |

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)

## 4. Device Description:

The Resona R9, Resona R9 Exp, Resona R9 Pro, Resona R9S, Nuewa R9, Nuewa R9 Exp, Nuewa R9 Pro, Nuewa R9S, Resona 7, Resona 7CV, Resona 7EXP, Resona 7S, Resona 7OB, Resona 7PRO, Imagyn 7, Resona Y, Resona R9W, Resona R7W, Nuewa R9W, Nuewa R7W Diagnostic Ultrasound System is a general purpose, mobile, software controlled, ultrasonic diagnostic system.

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

The safety and effectiveness of the new transducers is equivalent with predicate devices.

The materials used in the new transducers and needle-guided brackets were the same as in the predicate device. And the transducers were testing for biocompatibility.

All the transducers and needle-guided brackets were provided non-sterile to the end user. And all the disinfection/sterilization methods for the new transducers and needle guide brackets were provided to the end user and the users are notified that disinfection /sterilizaiton are necessary in the Operation Manual.

## 5. Intended Use:

Resona R9/Resona R9 Exp/Resona R9 Pro/Resona R9S/Nuewa R9/Nuewa R9 Exp/Nuewa R9 Pro/Nuewa R9S/Resona 7/Resona 7CV/Resona 7EXP/Resona

7S/Resona 7OB/Resona 7PRO/Imagyn 7/Resona Y/ Resona R9W/ Resona R7W/ Nuewa R9W/ Nuewa R7W Diagnostic Ultrasound System is applicable for adults, pregnant women, pediatric patients and neonates. It is intended for use in fetal, abdominal, Intra-operative, 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 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 (Pulse wave Doppler), CWD (Continuous wave Doppler), 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(Real-time 3D), iScape View, TDI (Tissue Doppler Imaging), Color M, Strain Elastography, Contrast imaging (Contrast agent for LVO(Left Ventricular Opacification)), V Flow (Vector Flow), STE(Sound Touch Elastography), STQ(Sound Touch Quantification), Contrast imaging (Contrast agent for Liver).

## 6. Summary of Modifications and New Added Features

This submission device is a modification to Resona R9, Resona R9 Exp, Resona R9 Pro, Resona R9S, Nuewa R9, Nuewa R9 Exp, Nuewa R9 Pro, Nuewa R9S, Resona 7, Resona 7CV, Resona 7EXP, Resona 7S, Resona 7OB, Resona 7PRO, Imagyn 7, Resona Y Diagnostic Ultrasound System previously cleared in K202785.

The new features:

| No. | New features |
|---|---|
| 1. | Add new models Resona R9W, Resona R7W, Nuewa R9W, Nuewa R7W |
| 2. | Add new transducers P8-2Ts, P8-2U, SD8-1U, SC9-2U，L15-3WU and needle-guided bracket NGB-039, NGB-058 |
| 3. | The material of DE10-3WU was changed. |
| 4. | Add Trans-vaginal clinical application to transducers ELC13-4U |
| 5. | Add CWD to transducers L14-3WU, L15-3WU, SC8-2U, SC6-1U, SD8-1U |
| 6. | Add STQ function to transducers ELC13-4U(Trans-rectal), V11-3HU (Trans-rectal, Trans-vaginal, Urology ), DE10-3WU(Trans-rectal, Trans-vaginal, Urology ) |
| 7. | Add Fusion Imaging to SC9-2U and Needle Navigation NB-058 (configured with Fusion Imaging) |

| | | |
|---|---|---|
| 8. | New Added Features | CEUS Chrono-Parametric Mode |
| 9. | | Tissue-Contrast Mix Rendering |
| 10. | | FH Tissue Tracking QA |
| 11. | | UltraSound ATtenuation analysis |
| 12. | | HepatoRenal Index Plus |
| 13. | | 3D-Print Format function (Physical/3D printed models generated from the digital output files are not for diagnostic use) |
| 14. | | Biopsy Grid |
| 15. | the other New changes | M-Ref. E Compare |
| 16. | | M-Ref. C&E |
| 17. | | DICOM Urology SR |
| 18. | | STE-HiRE |
| 19. | | iScanHelper function |

**Brief summary of the new features**

| | **Brief description of the features** | **Performance testing** | **Measurement accuracy** |
|---|---|---|---|
| FH Tissue Tracking QA | FH Tissue Tracking QA (Fetal Heart Tissue Tracking and Quantitative Analysis) is a quantitative assessment tool specifically made for fetal heart analysis based on the speckle tracking method. This tool is used to automatically track the motion of the left ventricular wall in a 4-chamber view cardiac cine and calculate the long-axis strain, strain rate, and other relevant parameters that reflects the contractile function of the left ventricle. | Obtain 10 fetal heart B mode image samples, compare the manual-obtained and FH TTQA-obtained values. Calculate the deviation between manual and FH TTQA. | The bias should be within ± 20%. |
| UltraSound ATtenuation analysis | It is used to measure the acoustic attenuation coefficient value of the target liver region and display its 2D spatial distribution, according to the ultrasonic echo signal. | Select four groups of phantom with different acoustic attenuation values, measure the acoustic attenuation value, calculate the deviation between the measured value | The bias should be within ±5%. |

| | | | |
|---|---|---|---|
| | | and the calibrated value of the phantom. | |
| HepatoRenal Index Plus | It is used to manually calculate the brightness ratio of the hepatic parenchyma and renal cortex based on the radiofrequency data. After the ROI of the hepatic parenchyma and renal cortex areas are located and confirmed by the doctor, the HRI+ calculates and displays the echo signal intensity ratio of the selected areas, and then determines the brightness ratio. | Select four groups of H/R-ROIs with diffierent gray-scales in a phantom, calculate the deviation between the measured value and the target value of the phantom. | The bias should be within ±10% |

## 7. Comparison with Predicate Devices:

The modified Resona R9, Resona R9 Exp, Resona R9 Pro, Resona R9S, Nuewa R9, Nuewa R9 Exp, Nuewa R9 Pro, Nuewa R9S, Resona 7, Resona 7CV, Resona 7EXP, Resona 7S, Resona 7OB, Resona 7PRO, Imagyn 7, Resona Y, Resona R9W, Resona R7W, Nuewa R9W, Nuewa R7W Diagnostic Ultrasound System is comparable with and substantially equivalent to these predicate devices:

| Device | Manufacturer | Model | 510(k) Number |
|---|---|---|---|
| 1. Main predicate device | Mindray | Resona R9 | K202785 |
| 2. Reference device | Mindray | Resona I9 | K210699 |
| 3. Reference device | GE | Voluson E10 | K192159 |
| 4. Reference device | GE | LOGIQ E10 | K211488 |
| 5. Reference device | Mindray | Hepatus 7 | K200643 |
| 6. Reference device | MylabTwice | 6200 | K100931 |
| 7. Reference device | Philips | EPIQ | K212704 |

- Resona R9, Resona R9 Exp, Resona R9 Pro, Resona R9S, Nuewa R9, Nuewa R9 Exp, Nuewa R9 Pro, Nuewa R9S, Resona 7, Resona 7CV, Resona 7EXP, Resona 7S, Resona 7OB, Resona 7PRO, Imagyn 7, Resona Y, Resona R9W, Resona R7W, Nuewa R9W, Nuewa R7W has the same technological characteristics, are comparable in key safety and effectiveness features, and have the same intended uses and basic operating modes. 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, and calculations. The subject device also has the same intended uses and basic operating modes as the predicate devices. Subject device Resona R9, Resona R9

Exp, Resona R9 Pro, Resona R9S, Nuewa R9, Nuewa R9 Exp, Nuewa R9 Pro, Nuewa R9S, Resona 7, Resona 7CV, Resona 7EXP, Resona 7S, Resona 7OB, Resona 7PRO, Imagyn 7, Resona Y, Resona R9W, Resona R7W, Nuewa R9W, Nuewa R7W has the same intended uses as the predicated device Resona R9 (K202785).

- The patient contact materials of the transducers are tested under ISO 10993-1.
- The acoustic power levels of Resona R9, Resona R9 Exp, Resona R9 Pro, Resona R9S, Nuewa R9, Nuewa R9 Exp, Nuewa R9 Pro, Nuewa R9S, Resona 7, Resona 7CV, Resona 7EXP, Resona 7S, Resona 7OB, Resona 7PRO, Imagyn 7, Resona Y , Resona R9W, Resona R7W, Nuewa R9W, Nuewa R7W are below the limits of FDA, which are the same as the predicated device Resona R9 (K202785).
- Resona R9, Resona R9 Exp, Resona R9 Pro, Resona R9S, Nuewa R9, Nuewa R9 Exp, Nuewa R9 Pro, Nuewa R9S, Resona 7, Resona 7CV, Resona 7EXP, Resona 7S, Resona 7OB, Resona 7PRO, Imagyn 7, Resona Y, Resona R9W, Resona R7W, Nuewa R9W, Nuewa R7W is designed in compliance with the FDA recognized electrical and physical safety standards, which are the same as the predicated device Resona R9 (K202785).
- The Resona R9, Resona R9 Exp, Resona R9 Pro, Resona R9S, Nuewa R9, Nuewa R9 Exp, Nuewa R9 Pro, Nuewa R9S, Resona 7, Resona 7CV, Resona 7EXP, Resona 7S, Resona 7OB, Resona 7PRO, Imagyn 7, Resona Y, Resona R9W, Resona R7W, Nuewa R9W, Nuewa R7W has the same imaging modes as the predicated devices.
- The Resona R9, Resona R9 Exp, Resona R9 Pro, Resona R9S, Nuewa R9, Nuewa R9 Exp, Nuewa R9 Pro, Nuewa R9S, Resona 7, Resona 7CV, Resona 7EXP, Resona 7S, Resona 7OB, Resona 7PRO, Imagyn 7, Resona Y, Resona R9W, Resona R7W, Nuewa R9W, Nuewa R7W has the same functions as the predicated devices.

| **Functions** | **Predicated devices** |
|---|---|
| CEUS Chrono-Parametric Mode | Parametric Imaging&LOGIQ E10 1099(K211488) |
| Tissue-Contrast Mix Rendering | CCIS &Voluson E10(K192159) |
| FH Tissue Tracking QA | FetalHQ & Voluson E10 (K192159) |
| UltraSound ATtenuation analysis | LiSA: Liver Ultra-Sound Attenuation & Hepatus 7(K200643) |
| HepatoRenal Index Plus | HRI& EPIQ (K212704) |
| Biopsy Grid | Biopsy Guide &Resona R9(K202785) |
| 3D-Print Format function | 3D Printing &Voluson E10(K192159) |
| Add Fusion Imaging to SC9-2U and Needle Navigation NB-058 | Fusion Imaging &Resona R9(K202785) |

| | |
|---|---|
| (configured with Fusion Imaging) | |

- The Resona R9, Resona R9 Exp, Resona R9 Pro, Resona R9S, Nuewa R9, Nuewa R9 Exp, Nuewa R9 Pro, Nuewa R9S, Resona 7, Resona 7CV, Resona 7EXP, Resona 7S, Resona 7OB, Resona 7PRO, Imagyn 7, Resona Y, Resona R9W, Resona R7W, Nuewa R9W, Nuewa R7W has similar tranducers with the predicated devices.

| **Subject Device Resona R9** | **Reference device** |
|---|---|
| P8-2Ts | P7-3Ts&Resona R9(K202785) |
| P8-2U | P7-3U&Resona R9(K202785) |
| SD8-1U | D8-2U& Resona R9(K202785) |
| SC9-2U | SC8-2U&Resona R9(K202785) |
| L15-3WU | L14-3WU&Resona R9(K202785) |

## 8. Non-clinical Tests:

Resona R9, Resona R9 Exp, Resona R9 Pro, Resona R9S, Nuewa R9, Nuewa R9 Exp, Nuewa R9 Pro, Nuewa R9S, Resona 7, Resona 7CV, Resona 7EXP, Resona 7S, Resona 7OB, Resona 7PRO, Imagyn 7, Resona Y , Resona R9W, Resona R7W, Nuewa R9W, Nuewa R7W 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 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 - 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.

## 9. Clinical Studies

Not applicable. The subject of this submission, Resona R9, Resona R9 Exp, Resona R9 Pro, Resona R9S, Nuewa R9, Nuewa R9 Exp, Nuewa R9 Pro, Nuewa R9S, Resona 7, Resona 7CV, Resona 7EXP, Resona 7S, Resona 7OB, Resona 7PRO, Imagyn 7, Resona Y, Resona R9W, Resona R7W, Nuewa R9W, Nuewa R7W Diagnostic Ultrasound System, does not require clinical studies to support substantial equivalence.

## 10. Summary

Based on the performance data as documented in the study, the Resona R9 series Diagnostic Ultrasound system was found to have a safety and effectiveness profile that is similar to the predicate device.

## 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 R9, Resona R9 Exp, Resona R9 Pro, Resona R9S, Nuewa R9, Nuewa R9 Exp, Nuewa R9 Pro, Nuewa R9S, Resona 7, Resona 7CV, Resona 7EXP, Resona 7S, Resona 7OB, Resona 7PRO, Imagyn 7, Resona Y, Resona R9W, Resona R7W, Nuewa R9W, Nuewa R7W Diagnostic Ultrasound System is substantially equivalent with respect to safety and effectiveness to primary predicate device Resona R9.