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

April 8, 2021

Re: K202785
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 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 1, 2020
Received: March 8, 2021

Dear Ma Chao:

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,

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)*
K202785

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 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 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, 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(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.**

# 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: **K202785**

## 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

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**Contact Person:**
Ma Chao
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:** April 05, 2021

## 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 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 7 Diagnostic Ultrasound System (predicate devices) that are already cleared by FDA, and they are listed below. Resona 7 is the main predicate devices.

| Device | Manufacturer | Model | Device Class | Product Code | 510(k) 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 | M6 | II | IYN, IYO, ITX | K171579 |
| 4. Reference device | Mindray | MX7 | II | IYN, IYO, ITX | K200001 |
| 5. Reference device | Mindray | M9 | II | IYN, IYO, ITX | K171034 |
| 6. Reference device | Samsung | RS85 | II | IYN, IYO, ITX | K192903 |
| 7. Reference device | Easote S.P.A | MylabTwice | II | IYN, IYO, ITX | K163082 |
| 8. Reference device | Philips | EPIQ 7 | II | IYN, IYO, ITX | K182857 |
| 9. Reference device | SuperSonic | Aixplorer | II | IYN, IYO, ITX | K173021 |
| 10. Reference device | GE | LOGIQ E9 | II | IYN, IYO, ITX | K163077 |
| 11. Reference device | GE | VOLUSON E8 | II | IYN, IYO, ITX | K181985 |
| 12. Reference device | Mindray | TE7 | II | IYN, IYO, ITX | K143472 |
| 13. Reference device | Mindray | DC-80A | II | IYN, IYO, ITX | K201693 |

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 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 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. And the 7LT4s, P8-3Ts has been cleared in FDA.

The materials used in the new transducers (except for ELC13-4U) and needle-guided brackets were the same as in the predicate device. And the ELC13-4U transducer was 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 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, 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(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. 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 171233.

The new features:

| No. | New features |
|---|---|
| 1. | Add new models Resona R9, Resona R9 Exp, Resona R9 Pro, Resona R9S, Nuewa R9, Nuewa R9 Exp, Nuewa R9 Pro, Nuewa R9S, Resona 7PRO, Imagyn 7, Resona Y |
| 2. | Add new transducers ELC13-4U, L14-3WU, DL14-3U, C6-2Gs, 7LT4s, P8-3Ts, L13-3WU and needle-guided bracket NGB-010, NGB-029, NGB-035, NGB-042, NGB-051, NGB-054 |
| 3. | Cancel transducers DE11-3U and needle-guided bracket NGB-027 |

| | | |
|---|---|---|
| 4. | Add Urology clinical application to Convex transducers C5-1U, C6-2GU, DE10-3U, DE10-3WU, SC5-1U and SC6-1U | |
| 5. | Add Peripheral vessel and Urology clinical application to Convex transducers SC8-2U and C4-1U | |
| 6. | Add Abdominal clinical application to Linear transducers L20-5U | |
| 7. | Add Pediatric and Neonatal Cephalic clinical application to Phased transducers P10-4U | |
| 8. | Add Peripheral vessel clinical application to CW transducers CW5s | |
| 9. | Add CWD to transducers L14-5WU and L20-5U | |
| 10. | Add Biopsy Guidance to transducers D8-4U and L14-5WU | |
| 11. | Add Contrast imaging (Contrast agent for Liver) function to transducers SC8-2U, L11-3U, L9-3U, L14-5WU and C11-3U | |
| 12. | Add Strain Elastography function to transducers L20-5U (Small Organ), L14-5WU (Peripheral vessel), L16-4HU, L16-4Hs and DE10-3WU | |
| 13. | Add STE function to transducers L9-3U, V11-3HU, L20-5U, L14-5WU (Peripheral vessel), C6-2GU, C4-1U and DE10-3WU | |
| 14. | Add STQ function to transducers L9-3U, L20-5U, L14-5WU, C6-2GU, and C4-1U | |
| 15. | Add Ultrasound Fusion Imaging function to transducers V11-3HU and C6-2GU | |
| 16. | Add Needle Navigation function to transducers C5-1U, SC8-2U, SP5-1U, C6-2GU and C4-1U | |
| 17. | New Added Features | HiFR CEUS |
| 18. | | Endocavity STE |
| 19. | | High frame rate STE |
| 20. | | Smart V Trace |
| 21. | | Smart ICV |
| 22. | | Smart Scene 3D |
| 23. | | Endocavity Fusion Imaging |
| 24. | | AutoEF |
| 25. | | Glazing Flow |
| 26. | | Ultra-Micro Angiography |

| | | |
|---|---|---|
| 27. | | Smart Fetal HR |
| 28. | | iClear$^{+}$ |
| 29. | | Smart Hip |
| 30. | | Smart HRI |
| 31. | | Smart Caliper |
| 32. | | Smart Trace |
| 33. | | McAfee |
| 34. | | V access |
| 35. | | CPP |
| 36. | | DICOM Small Parts SR |
| 37. | | Battery |

## 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 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 7 | K171233 |
| 2. Reference device | Mindray | DC-80 | K192152 |
| 3. Reference device | Mindray | M6 | K171579 |
| 4. Reference device | Mindray | MX7 | K200001 |
| 5. Reference device | Mindray | M9 | K171034 |
| 6. Reference device | Samsung | RS85 | K192903 |
| 7. Reference device | Easote S.P.A | MylabTwice | K163082 |
| 8. Reference device | Philips | EPIQ 7 | K182857 |
| 9. Reference device | Supersonic | Aixplorer | K173021 |

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|---|---|---|---|
| 10. Reference device | GE | LOGIQ E9 | K163077 |
| 11. Reference device | GE | VOLUSON E8 | K181985 |
| 12. Reference device | Mindray | TE7 | K143472 |
| 13. Reference device | Mindray | DC-80A | K201693 |

- 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 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 has the same intended uses as the predicated device Resona 7 (K171233).

| **Items** | **Subject Device Resona R9 series** | **Predicate device Resona 7 (K171233)** | **S/ D** |
|---|---|---|---|
| Indications for 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 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, | The Resona 7/Resona 7CV/Resona 7EXP/Resona 7S/Resona 7OB 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. | S |

| | | | |
|---|---|---|---|
| | 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. | 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(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). | 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(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 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 are below the limits of FDA, which are the same as the predicated device Resona 7 (K171233).
- 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 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 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 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 has the same functions as the predicated devices.

| **Functions** | **Predicated devices** |
|---|---|
| Endocavity STE | SE12-3&Aixplorer(K173021) |
| Smart V Trace | Voluson E8(K181985) |
| Smart ICV | Voluson E8(K181985) |
| Endocavity Fusion Imaging | IC5-9-D&LOGIQ E9(K163077) |
| AutoEF | DC-80(K192152) |
| Glazing Flow | DC-80(K192152) |
| Ultra-Micro Angiography | RS85（K192903） |
| Smart Fetal HR | Resona 7(K171233) |
| iClear+ | Resona 7(K171233) |
| Smart Hip | Resona 7(K171233) |
| Smart HRI | RS85（K192903） |
| Smart Caliper | Resona 7(K171233) |
| Smart Trace | Resona 7(K171233) |
| V access | M9(K171034) |

- 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 has similar tranducers with the predicated devices.

| **Subject Device Resona R9** | **Reference device** |
|---|---|
| ELC13-4U_L | 6LB7E_L&DC-80(K192152) |
| ELC13-4U_C | 6LB7E_C&DC-80(K192152) |
| L14-3WU | L11-3U&Resona 7(K171233) |
| L13-3WU | L11-3U&Resona 7(K171233) |
| DL14-3U | VL13-5&EPIQ 7(K182857) |
| C6-2Gs | C6-2GU&Resona 7(K171233)<br>C5-1s&MX7(K200001) |
| 7LT4s | 7LT4s&M6(K171579) |
| P8-3Ts | P8-3Ts&M9(K171034) |

## 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 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.
- AAMI / ANSI / ISO 10993-1:2009/(R)2013, biological evaluation of medical devices - part 1: evaluation and testing within a risk management process.
- AAMI / ANSI / IEC 62304:2015, 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 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 Diagnostic Ultrasound System is substantially equivalent with respect to safety and effectiveness to devices currently cleared for market.