



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

January 2, 2018

Re: K172860

Trade/Device Name: Resona 6/Resona 6T/Resona 6EXP/Resona 6Elite/Resona 6S/Resona
6PRO/Resona 6OB/Resona 5/Resona 5T/Resona 5EXP/Resona 5Elite
Diagnostic Ultrasound System

Regulation Number: 21 CFR 892.1550

Regulation Name: Ultrasonic pulsed doppler imaging system

Regulatory Class: II

Product Code: IYN, IYO, ITX

Dated: December 1, 2017

Received: December 4, 2017

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. 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); good

manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). 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 (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

A handwritten signature in blue ink that reads "Michael D. O'Hara". The signature is written over a large, light blue "FDA" watermark. To the right of the signature, the word "For" is printed in a small, black, sans-serif font.

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K172860

Device Name

Resona 6/Resona 6T/Resona 6EXP/Resona 6Elite/Resona 6S/Resona 6PRO/Resona 6OB/Resona 5/Resona 5T/Resona 5EXP/Resona 5Elite Diagnostic Ultrasound System

Indications for Use (Describe)

The Resona 6/Resona 6T/Resona 6EXP/Resona 6Elite/Resona 6S/Resona 6PRO/Resona 6OB/Resona 5/Resona 5T/Resona 5EXP/Resona 5Elite 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), adult cephalic, trans-rectal, trans-vaginal, musculo-skeletal (conventional, superficial), adult and pediatric cardiac, peripheral vessel, urology exam.

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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Diagnostic Ultrasound Indications For Use Format

System: Resona 6/Resona 6T/Resona 6EXP/Resona 6Elite/Resona 6S/Resona 6PRO/Resona 6OB/Resona 5/Resona 5T/Resona 5EXP/Resona 5Elite Diagnostic Ultrasound System

Transducer: N/A

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	N	N	N		N	N	N	Note 1, 2, 3, 4, 5, 6, 7,
	Abdominal	N	N	N	N	N	N	N	Note 1, 2, 3, 4, 5, 6, 7, 10, 14
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	N	N	N		N	N	N	Note 1, 2, 4, 7
	Small Organ (Specify**)	N	N	N		N	N	N	Note 1, 2, 4, 7, 8, 12, 13
	Neonatal Cephalic								
	Adult Cephalic	N	N	N	N	N	N	N	Note 1, 2, 4, 5, 6, 7, 10
	Trans-rectal	N	N	N		N	N	N	Note 1, 2, 3, 4, 6, 7
	Trans-vaginal	N	N	N		N	N	N	Note 1, 2, 3, 4, 6, 7
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	N	N	N		N	N	N	Note 1, 2, 4, 6, 7, 8, 10, 12, 13
	Musculo-skeletal (Superficial)	N	N	N		N	N	N	Note 1, 2, 4, 7, 8, 12, 13
	Intravascular								
Cardiac	Cardiac Adult	N	N	N	N	N	N	N	Note 1, 2, 4, 5, 6, 7, 9, 10
	Cardiac Pediatric	N	N	N	N	N	N	N	Note 1, 2, 4, 5, 6, 7, 10
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel	N	N	N		N	N	N	Note 1, 2, 4, 6, 7, 8, 10, 11, 12, 13
	Other (Specify***)	N	N	N		N	N	N	Note 1, 2, 4, 6, 7

N=new indication; P=previously cleared by FDA (K171233); E=added under Appendix E

Additional comments: Combined modes--B+M、PW+B、Color + B、Power + B、PW +Color+ B、Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testes.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging.

Note 2: Smart3D

Note 3:4D(Real-time 3D)

Note 4: iScape

Note 5: TDI

Note 6: Color M

Note 7: Biopsy Guidance

Note8: Strain Elastography

Note 9: Contrast imaging (Contrast agent for LVO)

Note 10: Ultrasound Fusion Imaging

Note 11: V Flow

Note12: STE

Note13: STQ

Note14: Contrast imaging (Contrast agent for Liver)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription USE (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications For Use Format

System: Resona 6/Resona 6T/Resona 6EXP/Resona 6Elite/Resona 6S/Resona 6PRO/Resona 6OB/Resona 5/Resona 5T/Resona 5EXP/Resona 5Elite Diagnostic Ultrasound System

Transducer: C5-1U

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	P	P	P		P	P	P	Note 1, 2, 4, 6, 7,10
	Abdominal	P	P	P		P	P	P	Note 1, 2, 4, 6, 7,10,14
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify**)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	P	P	P		P	P	P	Note 1, 2, 4, 6, 7,10
	Musculo-skeletal (Superficial)								
	Intravascular								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel	P	P	P		P	P	P	Note 1, 2, 4, 6, 7,10
	Other (Specify***)								

N=new indication; P=previously cleared by FDA (K171233); E=added under Appendix E

Additional comments: Combined modes--B+M、PW+B、Color + B、Power + B、PW +Color+ B、Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular.

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription USE (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications For Use Format

System: Resona 6/Resona 6T/Resona 6EXP/Resona 6Elite/Resona 6S/Resona 6PRO/Resona 6OB/Resona 5/Resona 5T/Resona 5EXP/Resona 5Elite Diagnostic Ultrasound System

Transducer: SC8-2U

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	P	P	P		P	P	P	Note 1, 2, 4, 5, 6, 10
	Abdominal	P	P	P		P	P	P	Note 1, 2, 4, 6, 10
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify**)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel								
	Other (Specify***)								

N=new indication; P=previously cleared by FDA (K171233); E=added under Appendix E

Additional comments: Combined modes--B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testes.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging.

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription USE (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications For Use Format

System: Resona 6/Resona 6T/Resona 6EXP/Resona 6Elite/Resona 6S/Resona 6PRO/Resona 6OB/Resona 5/Resona 5T/Resona 5EXP/Resona 5Elite Diagnostic Ultrasound System

Transducer: V11-3HU

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	P	P	P		P	P	P	Note 1, 2, 4, 6, 7
	Abdominal								
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify**)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal	P	P	P		P	P	P	Note 1, 2, 4, 6, 7
	Trans-vaginal	P	P	P		P	P	P	Note 1, 2, 4, 6, 7
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel								
	Other (Specify***)	P	P	P		P	P	P	Note 1, 2, 4, 6, 7

N=new indication; P=previously cleared by FDA (K171233); E=added under Appendix E

Additional comments: Combined modes--B+M、PW+B、Color + B、Power + B、PW +Color+ B、Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testes.

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Note 1: Tissue Harmonic Imaging.

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription USE (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications For Use Format

System: Resona 6/Resona 6T/Resona 6EXP/Resona 6Elite/Resona 6S/Resona 6PRO/Resona 6OB/Resona 5/Resona 5T/Resona 5EXP/Resona 5Elite Diagnostic Ultrasound System

Transducer: D8-4U

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	P	P	P		P	P	P	Note 1, 3, 4, 5, 6
	Abdominal	P	P	P		P	P	P	Note 1, 3, 4, 6
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify**)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel								
	Other (Specify***)								

N=new indication; P=previously cleared by FDA (K171233); E=added under Appendix E

Additional comments: Combined modes--B+M、PW+B、Color + B、Power + B、PW +Color+ B、Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testes.

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription USE (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications For Use Format

System: Resona 6/Resona 6T/Resona 6EXP/Resona 6Elite/Resona 6S/Resona 6PRO/Resona 6OB/Resona 5/Resona 5T/Resona 5EXP/Resona 5Elite Diagnostic Ultrasound System

Transducer: DE10-3U

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	P	P	P		P	P	P	Note 1, 3, 4, 6, 7
	Abdominal								
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify**)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal	P	P	P		P	P	P	Note 1, 3, 4, 6, 7
	Trans-vaginal	P	P	P		P	P	P	Note 1, 3, 4, 6, 7
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel								
	Other (Specify***)								

N=new indication; P=previously cleared by FDA (K171233); E=added under Appendix E

Additional comments: Combined modes--B+M、PW+B、Color + B、Power + B、PW +Color+ B、Power + PW +B.

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription USE (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications For Use Format

System: Resona 6/Resona 6T/Resona 6EXP/Resona 6Elite/Resona 6S/Resona 6PRO/Resona 6OB/Resona 5/Resona 5T/Resona 5EXP/Resona 5Elite Diagnostic Ultrasound System

Transducer: L14-6WU

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal	P	P	P		P	P	P	Note 1, 2, 4, 7
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	P	Note 1, 2, 4, 7
	Small Organ (Specify**)	P	P	P		P	P	P	Note 1, 2, 4, 7,8,12,13
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	P	P	P		P	P	P	Note 1, 2, 4, 7, 8,12,13
	Musculo-skeletal (Superficial)	P	P	P		P	P	P	Note 1, 2, 4, 7, 8,12,13
	Intravascular								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel	P	P	P		P	P	P	Note 1, 2, 4, 7
	Other (Specify***)								

N=new indication; P=previously cleared by FDA (K171233); E=added under Appendix E

Additional comments: Combined modes--B+M、PW+B、Color + B、Power + B、PW +Color+ B、Power + PW +B.

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Diagnostic Ultrasound Indications For Use Format

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Transducer: L11-3U

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal	P	P	P		P	P	P	Note 1, 2, 4, 7
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	P	Note 1, 2, 4, 7
	Small Organ (Specify**)	P	P	P		P	P	P	Note 1,2,4,7,8,12,13
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	P	P	P		P	P	P	Note 1, 2, 4, 7, 8,12,13
	Musculo-skeletal (Superficial)	P	P	P		P	P	P	Note 1, 2, 4, 7, 8,12,13
	Intravascular								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel	P	P	P		P	P	P	Note 1, 2, 4, 7, 11
	Other (Specify***)								

N=new indication; P=previously cleared by FDA (K171233); E=added under Appendix E

Additional comments: Combined modes--B+M、PW+B、Color + B、Power + B、PW +Color+ B、Power + PW +B.

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System: Resona 6/Resona 6T/Resona 6EXP/Resona 6Elite/Resona 6S/Resona 6PRO/Resona 6OB/Resona 5/Resona 5T/Resona 5EXP/Resona 5Elite Diagnostic Ultrasound System

Transducer: SP5-1U

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal	P	P	P	P	P	P	P	Note 1, 2, 4, 5, 6, 7,10
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify**)								
	Neonatal Cephalic								
	Adult Cephalic	P	P	P	P	P	P	P	Note 1, 2, 4, 5, 6, 7,10
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
Cardiac	Cardiac Adult	P	P	P	P	P	P	P	Note 1, 2, 4, 5, 6, 7,9,10
	Cardiac Pediatric	P	P	P	P	P	P	P	Note 1, 2, 4, 5, 6, 7,10
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel								
	Other (Specify***)								

N=new indication; P=previously cleared by FDA (K171233); E=added under Appendix E

Additional comments: Combined modes--B+M、PW+B、Color + B、Power + B、PW +Color+ B、Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testes.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging.

Note 2: Smart3D

Note 3:4D(Real-time 3D)

Note 4: iScape

Note 5: TDI

Note 6: Color M

Note 7: Biopsy Guidance

Note8: Strain Elastography

Note 9: Contrast imaging (Contrast agent for LVO)

Note 10: Ultrasound Fusion Imaging

Note 11: V Flow

Note12: STE

Note13: STQ

Note14: Contrast imaging (Contrast agent for Liver)

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription USE (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications For Use Format

System: Resona 6/Resona 6T/Resona 6EXP/Resona 6Elite/Resona 6S/Resona 6PRO/Resona 6OB/Resona 5/Resona 5T/Resona 5EXP/Resona 5Elite Diagnostic Ultrasound System

Transducer: DE11-3U

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	P	P	P		P	P	P	Note 1, 3, 4, 6, 7
	Abdominal								
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify**)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal	P	P	P		P	P	P	Note 1, 3, 4, 6, 7
	Trans-vaginal	P	P	P		P	P	P	Note 1, 3, 4, 6, 7
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel								
	Other (Specify***)								

N=new indication; P=previously cleared by FDA (K171233); E=added under Appendix E

Additional comments: Combined modes--B+M、PW+B、Color + B、Power + B、PW +Color+ B、Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testes.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging.

Note 2: Smart3D

Note 3:4D(Real-time 3D)

Note 4: iScape

Note 5: TDI

Note 6: Color M

Note 7: Biopsy Guidance

Note8: Strain Elastography

Note 9: Contrast imaging (Contrast agent for LVO)

Note 10: Ultrasound Fusion Imaging

Note 11: V Flow

Note12: STE

Note13: STQ

Note14: Contrast imaging (Contrast agent for Liver)

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription USE (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications For Use Format

System: Resona 6/Resona 6T/Resona 6EXP/Resona 6Elite/Resona 6S/Resona 6PRO/Resona 6OB/Resona 5/Resona 5T/Resona 5EXP/Resona 5Elite Diagnostic Ultrasound System

Transducer: SC5-1U

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	P	P	P		P	P	P	Note 1, 2, 4, 5, 6,7,10
	Abdominal	P	P	P		P	P	P	Note 1, 2, 4,6,7,10,14
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify**)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	P	P	P		P	P	P	Note 1, 2, 4,6,7,10
	Musculo-skeletal (Superficial)								
	Intravascular								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel	P	P	P		P	P	P	Note 1, 2, 4,6,7,10
	Other (Specify***)								

N=new indication; P=previously cleared by FDA (K171233); E=added under Appendix E

Additional comments: Combined modes--B+M、PW+B、Color + B、Power + B、PW +Color+ B、Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testes.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging.

Note 2: Smart3D

Note 3:4D(Real-time 3D)

Note 4: iScape

Note 5: TDI

Note 6: Color M

Note 7: Biopsy Guidance

Note8: Strain Elastography

Note 9: Contrast imaging (Contrast agent for LVO)

Note 10: Ultrasound Fusion Imaging

Note 11: V Flow

Note12: STE

Note13: STQ

Note14: Contrast imaging (Contrast agent for Liver)

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription USE (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications For Use Format

System: Resona 6/Resona 6T/Resona 6EXP/Resona 6Elite/Resona 6S/Resona 6PRO/Resona 6OB/Resona 5/Resona 5T/Resona 5EXP/Resona 5Elite Diagnostic Ultrasound System

Transducer: L20-5U

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify**)	P	P	P		P	P	P	Note 1, 2, 4
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	P	P	P		P	P	P	Note 1, 2, 4
	Musculo-skeletal (Superficial)	P	P	P		P	P	P	Note 1, 2, 4
	Intravascular								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel	P	P	P		P	P	P	Note 1, 2, 4
	Other (Specify***)								

N=new indication; P=previously cleared by FDA (K171233); E=added under Appendix E

Additional comments: Combined modes--B+M、PW+B、Color + B、Power + B、PW +Color+ B、Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testes.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging.

Note 2: Smart3D

Note 3:4D(Real-time 3D)

Note 4: iScape

Note 5: TDI

Note 6: Color M

Note 7: Biopsy Guidance

Note8: Strain Elastography

Note 9: Contrast imaging (Contrast agent for LVO)

Note 10: Ultrasound Fusion Imaging

Note 11: V Flow

Note12: STE

Note13: STQ

Note14: Contrast imaging (Contrast agent for Liver)

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription USE (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications For Use Format

System: Resona 6/Resona 6T/Resona 6EXP/Resona 6Elite/Resona 6S/Resona 6PRO/Resona 6OB/Resona 5/Resona 5T/Resona 5EXP/Resona 5Elite Diagnostic Ultrasound System

Transducer: L9-3U

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal	P	P	P		P	P	P	Note 1,2, 4,7
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	P	Note 1,2, 4,7
	Small Organ (Specify**)	P	P	P		P	P	P	Note 1,2, 4,7,8,12,13
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	P	P	P		P	P	P	Note 1,2, 4,7,8,12,13
	Musculo-skeletal (Superficial)	P	P	P		P	P	P	Note 1,2, 4,7,8,12,13
	Intravascular								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel	P	P	P		P	P	P	Note 1,2, 4,7,8,11,12,13
	Other (Specify***)								

N=new indication; P=previously cleared by FDA (K171233); E=added under Appendix E

Additional comments: Combined modes--B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular

**Small organ-breast, thyroid, testes,

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging. .

Note 2: Smart3D

Note 3:4D(Real-time 3D)

Note 4: iScape

Note5: TDI

Note6: Color M

Note7: Biopsy Guidance

Note8: Strain Elastography

Note9:Contrast imaging(contrast agent for LVO)

Note 10: Ultrasound Fusion Imaging

Note 11: V Flow

Note12: STE

Note13: STQ

Note14: Contrast imaging (Contrast agent for Liver)

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription USE (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications For Use Format

System: Resona 6/Resona 6T/Resona 6EXP/Resona 6Elite/Resona 6S/Resona 6PRO/Resona 6OB/Resona 5/Resona 5T/Resona 5EXP/Resona 5Elite Diagnostic Ultrasound System

Transducer: L14-5WU

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal	P	P	P		P	P	P	Note 1, 2, 4
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	P	Note 1, 2, 4
	Small Organ (Specify**)	P	P	P		P	P	P	Note 1, 2, 4, 8,12,13
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	P	P	P		P	P	P	Note 1, 2, 4, 8,12,13
	Musculo-skeletal (Superficial)	P	P	P		P	P	P	Note 1, 2, 4, 8,12,13
	Intravascular								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel	P	P	P		P	P	P	Note 1, 2, 4
	Other (Specify***)								

N=new indication; P=previously cleared by FDA (K171233); E=added under Appendix E

Additional comments: Combined modes--B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular

**Small organ-breast, thyroid, testes,

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging. .

Note 2: Smart3D

Note 3:4D(Real-time 3D)

Note 4: iScape

Note5: TDI

Note6: Color M

Note7: Biopsy Guidance

Note8: Strain Elastography

Note9:Contrast imaging(contrast agent for LVO)

Note 10: Ultrasound Fusion Imaging

Note 11: V Flow

Note12: STE

Note13: STQ

Note14: Contrast imaging (Contrast agent for Liver)

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription USE (Per 21 CFR 801.109)

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).

1. **Submitter:**

Shenzhen Mindray Bio-medical Electronics Co., LTD
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Nanshan, Shenzhen, 518057, P. R. China

Date Prepared: September 15, 2017

2. **Device Name:**

Resona 6/Resona 6T/Resona 6EXP/Resona 6Elite/Resona 6S/Resona 6PRO/Resona 6OB/Resona 5/Resona 5T/Resona 5EXP/Resona 5Elite 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. **Device Description:**

The Resona 6/Resona 6T/Resona 6EXP/Resona 6Elite/Resona 6S/Resona 6PRO/Resona 6OB/Resona 5/Resona 5T/Resona 5EXP/Resona 5Elite Diagnostic Ultrasound System is a general purpose, mobile, software controlled, ultrasonic diagnostic system. Its function is to acquire and display ultrasound images in

B-Mode, M-Mode, PW-Mode, CW-Mode, Color-Mode, Power/Dirpower Mode, THI, iScape mode, TDI mode, Color M, Strain Elastography, 3D/4D mode, Contrast imaging (Contrast agent for Liver), Contrast imaging (Contrast agent for LVO), Ultrasound Fusion Imaging, V Flow, STE, STQ or the combined mode (i.e. B/M-Mode, B/PW-mode, B/PW/Color).

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

4. Intended Use:

The Resona 6/Resona 6T/Resona 6EXP/Resona 6Elite/Resona 6S/Resona 6PRO/Resona 6OB/Resona 5/Resona 5T/Resona 5EXP/Resona 5Elite 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), adult cephalic, trans-rectal, trans-vaginal, musculo-skeletal (conventional, superficial), adult and pediatric cardiac, peripheral vessel, urology exam.

5. Comparison with Predicate Devices:

The Resona 6/Resona 6T/Resona 6EXP/Resona 6Elite/Resona 6S/Resona 6PRO/Resona 6OB/Resona 5/Resona 5T/Resona 5EXP/Resona 5Elite 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	M9	K171034

- Resona 6/Resona 6T/Resona 6EXP/Resona 6Elite/Resona 6S/Resona 6PRO/Resona 6OB/Resona 5/Resona 5T/Resona 5EXP/Resona 5Elite 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 6/Resona 6T/Resona 6EXP/Resona 6Elite/Resona 6S/Resona 6PRO/Resona 6OB/Resona 5/Resona 5T/Resona 5EXP/Resona 5Elite has the same intended uses as the predicated device Resona 7 (K171233).

Items	Subject Device Resona 6/Resona 6T/Resona 6EXP/Resona 6Elite/Resona 6S/Resona 6PRO/Resona 6OB/Resona 5/Resona 5T/Resona 5EXP/Resona 5Elite	Predicate device Resona 7 (K171233)
Intended Use	The Resona 6/Resona 6T/Resona 6EXP/Resona 6Elite/Resona 6S/Resona 6PRO/Resona 6OB/Resona 5/Resona 5T/Resona 5EXP/Resona 5Elite 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), adult cephalic, trans-rectal, trans-vaginal, musculo-skeletal (conventional, superficial), adult and pediatric cardiac, peripheral vessel, urology exam.	Resona 7 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 cephalic, adult cephalic,trans-rectal, trans-vaginal, musculo-skeletal (conventional, superficial), cardiac adult,cardiac pediatric, trans-esoph. (cardiac) ,peripheral vessel, and urology exams.

- The patient contact materials of the transducers are tested under ISO 10993-1.
- The acoustic power levels of Resona 6/Resona 6T/Resona 6EXP/Resona 6Elite/Resona 6S/Resona 6PRO/Resona 6OB/Resona 5/Resona 5T/Resona 5EXP/Resona 5Elite are below the limits of FDA, which are the same as the predicated device Resona 7 (K171233).
- Resona 6/Resona 6T/Resona 6EXP/Resona 6Elite/Resona 6S/Resona 6PRO/Resona 6OB/Resona 5/Resona 5T/Resona 5EXP/Resona 5Elite 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 6/Resona 6T/Resona 6EXP/Resona 6Elite/Resona 6S/Resona 6PRO/Resona 6OB/Resona 5/Resona 5T/Resona 5EXP/Resona 5Elite has the same imaging modes as the predicated devices.
- All of the functions of Resona 6/Resona 6T/Resona 6EXP/Resona 6Elite/Resona 6S/Resona 6PRO/Resona 6OB/Resona 5/Resona 5T/Resona 5EXP/Resona 5Elite are the same as the predicated devices.
- The Resona 6/Resona 6T/Resona 6EXP/Resona 6Elite/Resona 6S/Resona 6PRO/Resona 6OB/Resona 5/Resona 5T/Resona 5EXP/Resona 5Elite has similar transducers with the predicated devices.

6. Non-clinical Tests:

Resona 6/Resona 6T/Resona 6EXP/Resona 6Elite/Resona 6S/Resona 6PRO/Resona 6OB/Resona 5/Resona 5T/Resona 5EXP/Resona 5Elite 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).
- AAMI / ANSI / IEC 60601-1-2:2007/(R)2012, medical electrical equipment - part 1-2: general requirements for basic safety and essential performance - collateral standard: electromagnetic compatibility - requirements and tests (edition 3).
- 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 2.0 2007, 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 62304:2006, medical device software - software life cycle processes.
- AAMI / ANSI / IEC 62366:2007/(R)2013, 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.

7. Clinical Studies

Not applicable. The subject of this submission, Resona 6/Resona 6T/Resona 6EXP/Resona 6Elite/Resona 6S/Resona 6PRO/Resona 6OB/Resona 5/Resona 5T/Resona 5EXP/Resona 5Elite 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 Resona 6/Resona 6T/Resona 6EXP/Resona 6Elite/Resona 6S/Resona 6PRO/Resona 6OB/Resona 5/Resona 5T/Resona 5EXP/Resona 5Elite Diagnostic Ultrasound System is substantially equivalent with respect to safety and effectiveness to devices currently cleared for market.