



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street, NW
BUFFALO MN 55313

October 21, 2015

Re: K152763
Trade/Device Name: Resona 7/Resona 7CV/Resona 7EXP/Resona 7S/Resona 7OB
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: September 23, 2015
Received: September 24, 2015

Dear Mr. Job:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink that reads "Robert Ochs". The signature is written in a cursive, flowing style.

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)

K152763

Device Name

Resona 7/Resona 7CV/Resona 7EXP/Resona 7S/Resona 7OB

Indications for Use (Describe)

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, pediatric, small organ (breast, thyroid, testes), adult cephalic, trans-rectal, trans-vaginal, musculo-skeletal (conventional, superficial), cardiac adult, cardiac pediatric, peripheral vessel and urology exams.

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 7/Resona 7CV/Resona 7EXP/Resona 7S/Resona 7OB 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)	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 1,2,3,4,6,7,10
	Abdominal	N	N	N	N	N	N	N	Note 1,2,3,4,5,6,7,10
	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
	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, 7,10
	Musculo-skeletal (Superficial)	N	N	N		N	N	N	Note 1, 2, 4, 7
	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, 7,10,11
	Other (Specify***)	N	N	N		N	N	N	Note 1, 2, 4, 6, 7

N=new indication; P=previously cleared by FDA; 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:Static 3D/4D

Note 4: iScape

Note 5: TDI

Note 6: Color M

Note 7: Biopsy Guidance

Note 8: Elastography

Note 9: Contrast imaging (Contrast agent for LVO)

Note 10: Ultrasound Fusion Imaging

Note 11: V Flow

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

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

System: Resona 7/Resona 7CV/Resona 7EXP/Resona 7S/Resona 7OB 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)	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, 4, 6, 7,10
	Abdominal	N	N	N		N	N	N	Note 1, 2, 4, 6, 7,10
	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)	N	N	N		N	N	N	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	N	N	N		N	N	N	Note 1, 2, 4, 6, 7,10
	Other (Specify***)								

N=new indication; P=previously cleared by FDA; 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

Note 8: Elastography

Note 9: Contrast imaging (Contrast agent for LVO)

Note 10: Ultrasound Fusion Imaging

Note 11: V Flow

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

System: Resona 7/Resona 7CV/Resona 7EXP/Resona 7S/Resona 7OB 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)	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, 4, 6,10
	Abdominal	N	N	N		N	N	N	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; 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

Note 8: Elastography

Note 9: Contrast imaging (Contrast agent for LVO)

Note 10: Ultrasound Fusion Imaging

Note 11: V Flow

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

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

System: Resona 7/Resona 7CV/Resona 7EXP/Resona 7S/Resona 7OB 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)	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, 4, 6, 7
	Abdominal								
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify**)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal	N	N	N		N	N	N	Note 1, 2, 4, 6, 7
	Trans-vaginal	N	N	N		N	N	N	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***)	N	N	N		N	N	N	Note 1, 2, 4, 6, 7

N=new indication; P=previously cleared by FDA; 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

Note 8: Elastography

Note 9: Contrast imaging (Contrast agent for LVO)

Note 10: Ultrasound Fusion Imaging

Note 11: V Flow

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

System: Resona 7/Resona 7CV/Resona 7EXP/Resona 7S/Resona 7OB 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)	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, 3, 4, 6
	Abdominal	N	N	N		N	N	N	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; 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

Note 8: Elastography

Note 9: Contrast imaging (Contrast agent for LVO)

Note 10: Ultrasound Fusion Imaging

Note 11: V Flow

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

System: Resona 7/Resona 7CV/Resona 7EXP/Resona 7S/Resona 7OB 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)	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, 3, 4, 6, 7
	Abdominal								
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify**)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal	N	N	N		N	N	N	Note 1, 3, 4, 6, 7
	Trans-vaginal	N	N	N		N	N	N	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; 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)

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Note 7: Biopsy Guidance

Note 8: Elastography

Note 9: Contrast imaging (Contrast agent for LVO)

Note 10: Ultrasound Fusion Imaging

Note 11: V Flow

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

System: Resona 7/Resona 7CV/Resona 7EXP/Resona 7S/Resona 7OB 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)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal	N	N	N		N	N	N	Note 1, 2, 4, 7
	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
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	N	N	N		N	N	N	Note 1, 2, 4, 7
	Musculo-skeletal (Superficial)	N	N	N		N	N	N	Note 1, 2, 4, 7
	Intravascular								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel	N	N	N		N	N	N	Note 1, 2, 4, 7
	Other (Specify***)								

N=new indication; P=previously cleared by FDA; 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.

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

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Note 11: V Flow

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

System: Resona 7/Resona 7CV/Resona 7EXP/Resona 7S/Resona 7OB Diagnostic Ultrasound System

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)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal	N	N	N		N	N	N	Note 1, 2, 4, 7
	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
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	N	N	N		N	N	N	Note 1, 2, 4, 7
	Musculo-skeletal (Superficial)	N	N	N		N	N	N	Note 1, 2, 4, 7
	Intravascular								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel	N	N	N		N	N	N	Note 1, 2, 4, 7, 11
	Other (Specify***)								

N=new indication; P=previously cleared by FDA; 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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**Small organ-breast, thyroid, testes.

***Other use includes Urology.

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Note 2: Smart3D

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

System: Resona 7/Resona 7CV/Resona 7EXP/Resona 7S/Resona 7OB 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)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal	N	N	N	N	N	N	N	Note 1, 2, 4, 5, 6, 7,10
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify**)								
	Neonatal Cephalic								
	Adult Cephalic	N	N	N	N	N	N	N	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	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								
	Other (Specify***)								

N=new indication; P=previously cleared by FDA; 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)

System: Resona 7/Resona 7CV/Resona 7EXP/Resona 7S/Resona 7OB 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)	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, 3, 4, 6, 7
	Abdominal								
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify**)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal	N	N	N		N	N	N	Note 1, 3, 4, 6, 7
	Trans-vaginal	N	N	N		N	N	N	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; 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

Note 8: Elastography

Note 9: Contrast imaging (Contrast agent for LVO)

Note 10: Ultrasound Fusion Imaging

Note 11: V Flow

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

System: Resona 7/Resona 7CV/Resona 7EXP/Resona 7S/Resona 7OB 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)	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, 4,6,10
	Abdominal	N	N	N		N	N	N	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)	N	N	N		N	N	N	Note 1, 2, 4,6,10
	Musculo-skeletal (Superficial)								
	Intravascular								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel	N	N	N		N	N	N	Note 1, 2, 4,6,10
	Other (Specify***)								

N=new indication; P=previously cleared by FDA; 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

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Note 6: Color M

Note 7: Biopsy Guidance

Note 8: Elastography

Note 9: Contrast imaging (Contrast agent for LVO)

Note 10: Ultrasound Fusion Imaging

Note 11: V Flow

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

System: Resona 7/Resona 7CV/Resona 7EXP/Resona 7S/Resona 7OB 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)	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**)	N	N	N		N	N	N	Note 1, 2, 4
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	N	N	N		N	N	N	Note 1, 2, 4
	Musculo-skeletal (Superficial)	N	N	N		N	N	N	Note 1, 2, 4
	Intravascular								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel	N	N	N		N	N	N	Note 1, 2, 4
	Other (Specify***)								

N=new indication; P=previously cleared by FDA; 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

Note 8: Elastography

Note 9: Contrast imaging (Contrast agent for LVO)

Note 10: Ultrasound Fusion Imaging

Note 11: V Flow

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

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.

The assigned 510(k) number is:

1. Submitter:

Shenzhen Mindray Bio-medical Electronics Co., LTD
Mindray Building, Keji 12th Road South, Hi-tech Industrial Park, Nanshan, Shenzhen,
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Nanshan, Shenzhen, 518057, P. R. China

Date Prepared: August 26, 2015

2. Device Name: Resona 7/Resona 7CV/Resona 7EXP/Resona 7S/Resona 7OB

Diagnostic Ultrasound System

Classification

Regulatory Class: II

Review Category: Tier II

21 CFR 892.1550 Ultrasonic Pulsed Doppler Imaging System (90-IYN)

21 CFR 892.1560 Ultrasonic Pulsed Echo Imaging System (90-IYO)

21 CFR 892.1570 Diagnostic Ultrasound Transducer (90-ITX)

3. Device Description:

Resona 7/Resona 7CV/Resona 7EXP/Resona 7S/Resona 7OB Diagnostic Ultrasound System is a general purpose, mobile, software controlled, ultrasound 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, TDI mode, 3D/4D mode, Color M-mode,

iScape mode, Elastography, LVO, Ultrasound Fusion Imaging, V Flow or the combined mode (i.e. B/M-mode). This system is a Track 3 device that employs an array of probes that include linear array, convex array and phased array with a frequency range of approximately 3 MHz to 13.5MHz.

4. Intended Use:

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, pediatric, small organ (breast, thyroid, testes), adult cephalic, trans-rectal, trans-vaginal, musculo-skeletal (conventional, superficial), cardiac adult, cardiac pediatric, peripheral vessel and urology exams.

5. Comparison with Predicate Devices:

Resona 7/Resona 7CV/Resona 7EXP/Resona 7S/Resona 7OB Diagnostic Ultrasound System is comparable with and substantially equivalent to these predicate devices:

Predicate Device	Manufacturer	Model	510(k) Control Number
1	Mindray	DC-8	K150080
2	Mindray	M9	K141010
3	Mindray	DC-70	K150204
4	B-K Medical	1202	K132335
5	GE	Voluson E8	K132913
6	GE	LOGIQ E9	K142160

Resona 7/Resona 7CV/Resona 7EXP/Resona 7S/Resona 7OB Diagnostic Ultrasound System employs the same technology as the predicate devices. All systems transmit ultrasonic energy into patients, then 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 7/Resona 7CV/Resona 7EXP/Resona 7S/Resona 7OB has the same intended uses as the predicated device DC-8(K150080)

Items	Subject Device Resona 7/Resona 7CV/ Resona 7EXP/ Resona 7S/Resona 7OB	Predicate device DC-8 (K150080)
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Intended use	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, pediatric, small organ (breast, thyroid, testes), adult cephalic, trans-rectal, trans-vaginal, musculo-skeletal (conventional, superficial), cardiac adult, cardiac pediatric, peripheral vessel and urology exams.	The DC-8 diagnostic ultrasound system is applicable for adults, pregnant women, pediatric patients and neonates. It is intended for use in fetal, abdominal, pediatric, small organ (breast, thyroid, testes), neonatal cephalic, adult cephalic, trans-rectal, trans-vaginal, musculo-skeletal (conventional, superficial), cardiac adult, cardiac pediatric, peripheral vessel, urology and transesophageal (Cardiac) exams.
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- The patient contact materials of the transducers are tested under ISO 10993-1.
- The acoustic power levels of Resona 7/Resona 7CV/Resona 7EXP/Resona 7S/Resona 7OB are below the limits of FDA, which are the same as the predicated device DC-8(K150080).
- Resona 7/Resona 7CV/Resona 7EXP/Resona 7S/Resona 7OB is designed in compliance with the FDA recognized electrical and physical safety standards, which are the same as the predicated device DC-8(K150080).
- The Resona 7/Resona 7CV/Resona 7EXP/Resona 7S/Resona 7OB has the same imaging modes as the predicated devices.
- All of the functions of Resona 7/Resona 7CV/Resona 7EXP/Resona 7S/Resona 7OB are the same as the predicated devices.
- The Resona 7/Resona 7CV/Resona 7EXP/Resona 7S/Resona 7OB has similar transducers with the predicated devices.

7. Non-clinical Tests:

Resona 7/Resona 7CV/Resona 7EXP/Resona 7S/Resona 7OB 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 found to conform with applicable medical safety standards.

Non-clinical tests relied on in this premarket notification submission for a determination of substantial equivalence include testing showing compliance with the following standards:

- AAMI/ANSI ES60601-1: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2: Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic

compatibility - Requirements and tests (Edition 3)

- IEC 60601-2-37: Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
- IEC 62304: Medical device software - Software life cycle processes
- ISO14971: Medical devices - Application of risk management to medical devices
- UD 2: Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment Revision 3
- UD 3: Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
- ISO 10993-1: Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process

8. Clinical Tests:

Not Applicable.

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 7/Resona 7CV/Resona 7EXP/Resona 7S/Resona 7OB Diagnostic Ultrasound System is substantially equivalent with respect to safety and effectiveness to devices currently cleared for market.