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

October 25, 2017

Re: K172970
Trade/Device Name: M7/M7T/M7 Premium/M7 Expert/M7 Super 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 15, 2017
Received: September 26, 2017

Dear Yang Zhaohui:

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 (DICE) 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 (DICE) 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,

Michael D. O'Hara For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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)*

K172970

Device Name

M7/M7T/M7 Premium/M7 Expert/M7 Super Diagnostic Ultrasound System

Indications for Use *(Describe)*

The M7/M7T/M7 Premium/M7 Expert/M7 Super Diagnostic Ultrasound System is applicable for adults, pregnant women, pediatric patients and neonates. It is intended for use in gynecology, obstetric, abdominal, pediatric, small parts (breast, testes, thyroid), neonatal cephalic, transcranial, cardiac, transvaginal, transrectal, peripheral vascular, urology, orthopedic, and musculoskeletal(conventional and superficial), intraoperative and transesophageal(cardiac) 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 Form

System: M7/M7T/M7 Premium/M7 Expert/M7 Super 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/ Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P		P	P	Note 1,2,3,4,6,7
	Abdominal	P	P	P	P	P	P	Note 1,2,3,4,5,6,7,9
	Intraoperative (specify)*	P	P	P		P	P	Note1,2,4,6,7
	Intraoperative (Neuro)							
	Laparoscopic							
	Pediatric	P	P	P	P	P	P	Note 1,2,3,4,5,6,7
	Small organ(specify)**	P	P	P		P	P	Note 1,2,4,6,7,8
	Neonatal Cephalic	P	P	P	P	P	P	Note 1,2,4,5,6,7
	Adult Cephalic	P	P	P	P	P	P	Note 1,2,4,5,6,7
	Trans-rectal	P	P	P		P	P	Note 1,2,4,6,7
	Trans-vaginal	P	P	P		P	P	Note 1,2,4,6,7
	Trans-urethral							
	Trans-esoph.(non-Card.)							
	Musculo-skeletal Conventional	P	P	P	P	P	P	Note 1,2,4,5,6,7
	Musculo-skeletal Superficial	P	P	P		P	P	Note 1,2,4,6,7
	Intravascular							
	Other (specify)***	P	P	P		P	P	Note 1, 2, 4,6,7
Cardiac	Cardiac Adult	P	P	P	P	P	P	Note 1,2,5,6,7
	Cardiac Pediatric	P	P	P	P	P	P	Note 1,2,5,6,7
	Intravascular (Cardiac)							
	Trans-esoph.(Cardiac)	P	P	P	P	P	P	Note1,2,5,6
	Intra-Cardiac							
Peripheral Vascular	Peripheral Vascular	P	P	P		P	P	Note 1, 2, 4,6,7
	Other (specify)							

N=new indication; P=previously cleared by FDA(K131690, K171034); 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 (Liver Only)

Concurrence of CDRH, Office of Device Evaluation(ODE)

Diagnostic Ultrasound Indications for Use Form

System: M7/M7T/M7 Premium/M7 Expert/M7 Super Diagnostic Ultrasound System
Transducer: C5-2s
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/ Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P		P	P	Note 1, 2, 4,6,7
	Abdominal	P	P	P		P	P	Note 1, 2, 4,6,7,9
	Intraoperative (specify)*							
	Intraoperative (Neuro)							
	Laparoscopic							
	Pediatric	P	P	P		P	P	Note 1, 2, 4,6,7
	Small organ(specify)**							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph.(non-Card.)							
	Musculo-skeletal Conventional							
	Musculo-skeletal Superficial							
	Intravascular							
	Other (specify)***							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph.(Cardiac)							
	Intra-Cardiac							
Peripheral Vascular	Peripheral Vascular	P	P	P		P	P	Note 1, 2, 4,6,7
	Other (specify)							

N=new indication; P=previously cleared by FDA(K131690); 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 (Liver Only)

Concurrence of CDRH, Office of Device Evaluation(ODE)

Diagnostic Ultrasound Indications for Use Form

System: M7/M7T/M7 Premium/M7 Expert/M7 Super Diagnostic Ultrasound System
Transducer: V10-4s
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/ Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P		P	P	Note 1, 2, 4,6,7
	Abdominal							
	Intraoperative (specify)*							
	Intraoperative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small organ(specify)**							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	P	P	P		P	P	Note 1, 2, 4,6,7
	Trans-vaginal	P	P	P		P	P	Note 1, 2, 4,6,7
	Trans-urethral							
	Trans-esoph.(non-Card.)							
	Musculo-skeletal Conventional							
	Musculo-skeletal Superficial							
	Intravascular							
	Other (specify)***	P	P	P		P	P	Note 1, 2, 4,6,7
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph.(Cardiac)							
	Intra-Cardiac							
Peripheral Vascular	Peripheral Vascular							
	Other (specify)							

N=new indication; P=previously cleared by FDA(K131690); 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 (Liver Only)

Concurrence of CDRH, Office of Device Evaluation(ODE)

Diagnostic Ultrasound Indications for Use Form

System: M7/M7T/M7 Premium/M7 Expert/M7 Super Diagnostic Ultrasound System
Transducer: V10-4Bs
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/ Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P		P	P	Note 1, 2, 4,6,7
	Abdominal							
	Intraoperative (specify)*							
	Intraoperative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small organ(specify)**							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	P	P	P		P	P	Note 1, 2, 4,6,7
	Trans-vaginal	P	P	P		P	P	Note 1, 2, 4,6,7
	Trans-urethral							
	Trans-esoph.(non-Card.)							
	Musculo-skeletal Conventional							
	Musculo-skeletal Superficial							
	Intravascular							
	Other (specify)***	P	P	P		P	P	Note 1, 2, 4,6,7
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph.(Cardiac)							
	Intra-Cardiac							
Peripheral Vascular	Peripheral Vascular							
	Other (specify)							

N=new indication; P=previously cleared by FDA(K131690); 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 (Liver Only)

Concurrence of CDRH, Office of Device Evaluation(ODE)

Diagnostic Ultrasound Indications for Use Form

System: M7/M7T/M7 Premium/M7 Expert/M7 Super Diagnostic Ultrasound System
Transducer: 7L4s
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/ Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	P	P	P		P	P	Note 1,2, 4,6,7
	Intraoperative (specify)*							
	Intraoperative (Neuro)							
	Laparoscopic							
	Pediatric	P	P	P		P	P	Note 1,2, 4,6,7
	Small organ(specify)**	P	P	P		P	P	Note 1,2, 4,6,7
	Neonatal Cephalic	P	P	P		P	P	Note 1,2, 4,6,7
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph.(non-Card.)							
	Musculo-skeletal Conventional	P	P	P		P	P	Note 1,2, 4,6,7
	Musculo-skeletal Superficial	P	P	P		P	P	Note 1,2, 4,6,7
	Intravascular							
	Other (specify)***							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph.(Cardiac)							
	Intra-Cardiac							
Peripheral Vascular	Peripheral Vascular	P	P	P		P	P	Note 1,2, 4,6,7
	Other (specify)							

N=new indication; P=previously cleared by FDA(K131690); 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 (Liver Only)

Concurrence of CDRH, Office of Device Evaluation(ODE)

Diagnostic Ultrasound Indications for Use Form

System: M7/M7T/M7 Premium/M7 Expert/M7 Super Diagnostic Ultrasound System
Transducer: L14-6s
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/ Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intraoperative (specify)*							
	Intraoperative (Neuro)							
	Laparoscopic							
	Pediatric	P	P	P		P	P	Note 1,2, 4,6,7
	Small organ(specify)**	P	P	P		P	P	Note 1,2, 4,6,7
	Neonatal Cephalic	P	P	P		P	P	Note 1,2, 4,6,7
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph.(non-Card.)							
	Musculo-skeletal Conventional	P	P	P		P	P	Note 1,2, 4,6,7
	Musculo-skeletal Superficial	P	P	P		P	P	Note 1,2, 4,6,7
	Intravascular							
	Other (specify)***							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph.(Cardiac)							
	Intra-Cardiac							
Peripheral Vascular	Peripheral Vascular	P	P	P		P	P	Note 1,2, 4,6,7
	Other (specify)							

N=new indication; P=previously cleared by FDA(K131690); 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 (Liver Only)

Concurrence of CDRH, Office of Device Evaluation(ODE)

Diagnostic Ultrasound Indications for Use Form

System: M7/M7T/M7 Premium/M7 Expert/M7 Super Diagnostic Ultrasound System
Transducer: P4-2s
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/ Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	P	P	P	P	P	P	Note 1, 2,5,6,7
	Intraoperative (specify)*							
	Intraoperative (Neuro)							
	Laparoscopic							
	Pediatric	P	P	P	P	P	P	Note 1, 2,5,6,7
	Small organ(specify)**							
	Neonatal Cephalic	P	P	P	P	P	P	Note 1, 2,5,6,7
	Adult Cephalic	P	P	P	P	P	P	Note 1, 2,5,6,7
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph.(non-Card.)							
	Musculo-skeletal Conventional							
	Musculo-skeletal Superficial							
	Intravascular							
	Other (specify)***							
Cardiac	Cardiac Adult	P	P	P	P	P	P	Note 1, 2,5,6,7
	Cardiac Pediatric	P	P	P	P	P	P	Note 1, 2,5,6,7
	Intravascular (Cardiac)							
	Trans-esoph.(Cardiac)							
	Intra-Cardiac							
Peripheral Vascular	Peripheral Vascular							
	Other (specify)							

N=new indication; P=previously cleared by FDA(K131690); 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 (Liver Only)

Concurrence of CDRH, Office of Device Evaluation(ODE)

Diagnostic Ultrasound Indications for Use Form

System: M7/M7T/M7 Premium/M7 Expert/M7 Super Diagnostic Ultrasound System
Transducer: P7-3s
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/ Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	P	P	P	P	P	P	Note 1, 2,5,6
	Intraoperative (specify)*							
	Intraoperative (Neuro)							
	Laparoscopic							
	Pediatric	P	P	P	P	P	P	Note 1, 2,5,6
	Small organ(specify)**							
	Neonatal Cephalic	P	P	P	P	P	P	Note 1, 2,5,6
	Adult Cephalic	P	P	P	P	P	P	Note 1, 2,5,6
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph.(non-Card.)							
	Musculo-skeletal Conventional	P	P	P	P	P	P	Note 1, 2,5,6
	Musculo-skeletal Superficial							
	Intravascular							
	Other (specify)***							
Cardiac	Cardiac Adult	P	P	P	P	P	P	Note 1, 2,5,6
	Cardiac Pediatric	P	P	P	P	P	P	Note 1, 2,5,6
	Intravascular (Cardiac)							
	Trans-esoph.(Cardiac)							
	Intra-Cardiac							
Peripheral Vascular	Peripheral Vascular							
	Other (specify)							

N=new indication; P=previously cleared by FDA(K131690); 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 (Liver Only)

Concurrence of CDRH, Office of Device Evaluation(ODE)

Diagnostic Ultrasound Indications for Use Form

System: M7/M7T/M7 Premium/M7 Expert/M7 Super Diagnostic Ultrasound System
Transducer: 4CD4s
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/ Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P		P	P	Note1,2, 3, 4,6
	Abdominal	P	P	P		P	P	Note1,2, 3, 4,6
	Intraoperative (specify)*							
	Intraoperative (Neuro)							
	Laparoscopic							
	Pediatric	P	P	P		P	P	Note1,2, 3, 4,6
	Small organ(specify)**							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph.(non-Card.)							
	Musculo-skeletal Conventional							
	Musculo-skeletal Superficial							
	Intravascular							
	Other (specify)***							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph.(Cardiac)							
	Intra-Cardiac							
Peripheral Vascular	Peripheral Vascular							
	Other (specify)							

N=new indication; P=previously cleared by FDA(K131690); 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 (Liver Only)

Concurrence of CDRH, Office of Device Evaluation(ODE)

Diagnostic Ultrasound Indications for Use Form

System: M7/M7T/M7 Premium/M7 Expert/M7 Super Diagnostic Ultrasound System
Transducer: 6C2s
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/ Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	P	P	P		P	P	Note 1, 2, 4,6,7
	Intraoperative (specify)*							
	Intraoperative (Neuro)							
	Laparoscopic							
	Pediatric	P	P	P		P	P	Note 1, 2, 4,6,7
	Small organ(specify)**							
	Neonatal Cephalic	P	P	P		P	P	Note 1, 2, 4,6,7
	Adult Cephalic	P	P	P		P	P	Note 1, 2, 4,6,7
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph.(non-Card.)							
	Musculo-skeletal Conventional	P	P	P		P	P	Note 1, 2, 4,6,7
	Musculo-skeletal Superficial	P	P	P		P	P	Note 1, 2, 4,6,7
	Intravascular							
	Other (specify)***							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph.(Cardiac)							
	Intra-Cardiac							
Peripheral Vascular	Peripheral Vascular	P	P	P		P	P	Note 1, 2, 4,6,7
	Other (specify)							

N=new indication; P=previously cleared by FDA(K131690); 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 (Liver Only)

Concurrence of CDRH, Office of Device Evaluation(ODE)

Diagnostic Ultrasound Indications for Use Form

System: M7/M7T/M7 Premium/M7 Expert/M7 Super Diagnostic Ultrasound System
Transducer: 7L5s
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/ Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intraoperative (specify)*							
	Intraoperative (Neuro)							
	Laparoscopic							
	Pediatric	P	P	P		P	P	Note 1,2, 4,6,7
	Small organ(specify)**	P	P	P		P	P	Note 1,2, 4,6,7
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph.(non-Card.)							
	Musculo-skeletal Conventional	P	P	P		P	P	Note 1,2, 4,6,7
	Musculo-skeletal Superficial	P	P	P		P	P	Note 1,2, 4,6,7
	Intravascular							
	Other (specify)***							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph.(Cardiac)							
	Intra-Cardiac							
Peripheral Vascular	Peripheral Vascular	P	P	P		P	P	Note 1,2, 4,6,7
	Other (specify)							

N=new indication; P=previously cleared by FDA(K131690); 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 (Liver Only)

Concurrence of CDRH, Office of Device Evaluation(ODE)

Diagnostic Ultrasound Indications for Use Form

System: M7/M7T/M7 Premium/M7 Expert/M7 Super Diagnostic Ultrasound System
Transducer: L7-3s
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/ Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	P	P	P		P	P	Note 1,2, 4,6,7
	Intraoperative (specify)*							
	Intraoperative (Neuro)							
	Laparoscopic							
	Pediatric	P	P	P		P	P	Note 1,2, 4,6,7
	Small organ(specify)**	P	P	P		P	P	Note 1,2, 4,6,7
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph.(non-Card.)							
	Musculo-skeletal Conventional	P	P	P		P	P	Note 1,2, 4,6,7
	Musculo-skeletal Superficial	P	P	P		P	P	Note 1,2, 4,6,7
	Intravascular							
	Other (specify)***							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph.(Cardiac)							
	Intra-Cardiac							
Peripheral Vascular	Peripheral Vascular	P	P	P		P	P	Note 1,2, 4,6,7
	Other (specify)							

N=new indication; P=previously cleared by FDA(K131690); 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 (Liver Only)

Concurrence of CDRH, Office of Device Evaluation(ODE)

Diagnostic Ultrasound Indications for Use Form

System: M7/M7T/M7 Premium/M7 Expert/M7 Super Diagnostic Ultrasound System
Transducer: L12-4s
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/ Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	P	P	P		P	P	Note 1,2, 4,6,7
	Intraoperative (specify)*							
	Intraoperative (Neuro)							
	Laparoscopic							
	Pediatric	P	P	P		P	P	Note 1,2, 4,6,7
	Small organ(specify)**	P	P	P		P	P	Note 1,2, 4,6,7,8
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph.(non-Card.)							
	Musculo-skeletal Conventional	P	P	P		P	P	Note 1,2, 4,6,7
	Musculo-skeletal Superficial	P	P	P		P	P	Note 1,2, 4,6,7
	Intravascular							
	Other (specify)***							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph.(Cardiac)							
	Intra-Cardiac							
Peripheral Vascular	Peripheral Vascular	P	P	P		P	P	Note 1,2, 4,6,7
	Other (specify)							

N=new indication; P=previously cleared by FDA(K131690); 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 (Liver Only)

Concurrence of CDRH, Office of Device Evaluation(ODE)

Diagnostic Ultrasound Indications for Use Form

System: M7/M7T/M7 Premium/M7 Expert/M7 Super Diagnostic Ultrasound System
Transducer: L14-6Ns
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/ Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intraoperative (specify)*							
	Intraoperative (Neuro)							
	Laparoscopic							
	Pediatric	P	P	P		P	P	Note 1,2, 4,6,7
	Small organ(specify)**	P	P	P		P	P	Note 1,2, 4,6,7,8
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph.(non-Card.)							
	Musculo-skeletal Conventional	P	P	P		P	P	Note 1,2, 4,6,7
	Musculo-skeletal Superficial	P	P	P		P	P	Note 1,2, 4,6,7
	Intravascular							
	Other (specify)***							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph.(Cardiac)							
	Intra-Cardiac							
Peripheral Vascular	Peripheral Vascular	P	P	P		P	P	Note 1,2, 4,6,7
	Other (specify)							

N=new indication; P=previously cleared by FDA(K131690); 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 (Liver Only)

Concurrence of CDRH, Office of Device Evaluation(ODE)

Diagnostic Ultrasound Indications for Use Form

System: M7/M7T/M7 Premium/M7 Expert/M7 Super Diagnostic Ultrasound System
Transducer: P12-4s
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/ Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	P	P	P	P	P	P	Note 1, 2,5,6
	Intraoperative (specify)*							
	Intraoperative (Neuro)							
	Laparoscopic							
	Pediatric	P	P	P	P	P	P	Note 1, 2,5,6
	Small organ(specify)**							
	Neonatal Cephalic	P	P	P	P	P	P	Note 1, 2,5,6
	Adult Cephalic	P	P	P	P	P	P	Note 1, 2,5,6
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph.(non-Card.)							
	Musculo-skeletal Conventional							
	Musculo-skeletal Superficial							
	Intravascular							
	Other (specify)***							
Cardiac	Cardiac Adult	P	P	P	P	P	P	Note 1, 2,5,6
	Cardiac Pediatric	P	P	P	P	P	P	Note 1, 2,5,6
	Intravascular (Cardiac)							
	Trans-esoph.(Cardiac)							
	Intra-Cardiac							
Peripheral Vascular	Peripheral Vascular							
	Other (specify)							

N=new indication; P=previously cleared by FDA(K131690); 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 (Liver Only)

Concurrence of CDRH, Office of Device Evaluation(ODE)

Diagnostic Ultrasound Indications for Use Form

System: M7/M7T/M7 Premium/M7 Expert/M7 Super Diagnostic Ultrasound System
Transducer: CW2s
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/ Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intraoperative (specify)*							
	Intraoperative (Neuro)							
	Laparoscopic							
	Pediatric				P			
	Small organ(specify)**							
	Neonatal Cephalic							
	Adult Cephalic				P			
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph.(non-Card.)							
	Musculo-skeletal Conventional							
	Musculo-skeletal Superficial							
	Intravascular							
	Other (specify)***							
Cardiac	Cardiac Adult				P			
	Cardiac Pediatric				P			
	Intravascular (Cardiac)							
	Trans-esoph.(Cardiac)							
	Intra-Cardiac							
Peripheral Vascular	Peripheral Vascular							
	Other (specify)							

N=new indication; P=previously cleared by FDA(K131690); 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 (Liver Only)

Concurrence of CDRH, Office of Device Evaluation(ODE)

Diagnostic Ultrasound Indications for Use Form

System: M7/M7T/M7 Premium/M7 Expert/M7 Super Diagnostic Ultrasound System
Transducer: 7LT4s
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/ Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	P	P	P		P	P	Note1,2,4,6,7
	Intraoperative (specify)*	P	P	P		P	P	Note1,2,4,6,7
	Intraoperative (Neuro)							
	Laparoscopic							
	Pediatric	P	P	P		P	P	Note1,2,4,6,7
	Small organ(specify)**	P	P	P		P	P	Note1,2,4,6,7
	Neonatal Cephalic	P	P	P		P	P	Note1,2,4,6,7
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph.(non-Card.)							
	Musculo-skeletal Conventional	P	P	P		P	P	Note1,2,4,6,7
	Musculo-skeletal Superficial	P	P	P		P	P	Note1,2,4,6,7
	Intravascular							
	Other (specify)***							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph.(Cardiac)							
	Intra-Cardiac							
Peripheral Vascular	Peripheral Vascular	P	P	P		P	P	Note1,2,4,6,7
	Other (specify)							

N=new indication; P=previously cleared by FDA(K131690); 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 (Liver Only)

Concurrence of CDRH, Office of Device Evaluation(ODE)

Diagnostic Ultrasound Indications for Use Form

System: M7/M7T/M7 Premium/M7 Expert/M7 Super Diagnostic Ultrasound System
Transducer: P7-3Ts
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/ Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intraoperative (specify)*							
	Intraoperative (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							
	Other (specify)***							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph.(Cardiac)	P	P	P	P	P	P	Note1,2,5,6
	Intra-Cardiac							
Peripheral Vascular	Peripheral Vascular							
	Other (specify)							

N=new indication; P=previously cleared by FDA(K131690); 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 (Liver Only)

Concurrence of CDRH, Office of Device Evaluation(ODE)

Diagnostic Ultrasound Indications for Use Form

System: M7/M7T/M7 Premium/M7 Expert/M7 Super Diagnostic Ultrasound System
Transducer: C11-3s
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/ Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	P	P	P		P	P	Note 1,2,4,6,7
	Intraoperative (specify)*							
	Intraoperative (Neuro)							
	Laparoscopic							
	Pediatric	P	P	P		P	P	Note 1,2,4,6,7
	Small organ(specify)**							
	Neonatal Cephalic	P	P	P		P	P	Note 1,2,4,6,7
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph.(non-Card.)							
	Musculo-skeletal Conventional							
	Musculo-skeletal Superficial							
	Intravascular							
	Other (specify)***							
Cardiac	Cardiac Adult							
	Cardiac Pediatric	P	P	P		P	P	Note 1,2,4,6,7
	Intravascular (Cardiac)							
	Trans-esoph.(Cardiac)							
	Intra-Cardiac							
Peripheral Vascular	Peripheral Vascular	P	P	P		P	P	Note 1,2,4,6,7
	Other (specify)							

N=new indication; P=previously cleared by FDA(K171034); 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 (Liver Only)

Concurrence of CDRH, Office of Device Evaluation(ODE)

Diagnostic Ultrasound Indications for Use Form

System: M7/M7T/M7 Premium/M7 Expert/M7 Super Diagnostic Ultrasound System
Transducer: SP5-1s
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/ Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	P	P	P	P	P	P	Note 1,2,4,6,7
	Intraoperative (specify)*							
	Intraoperative (Neuro)							
	Laparoscopic							
	Pediatric	P	P	P	P	P	P	Note 1,2,4,6,7
	Small organ(specify)**							
	Neonatal Cephalic	P	P	P	P	P	P	Note 1,2,4,6,7
	Adult Cephalic	P	P	P	P	P	P	Note 1,2,4,6,7
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph.(non-Card.)							
	Musculo-skeletal Conventional							
	Musculo-skeletal Superficial							
	Intravascular							
	Other (specify)***							
Cardiac	Cardiac Adult	P	P	P	P	P	P	Note 1,2,4,5,6,7
	Cardiac Pediatric	P	P	P	P	P	P	Note 1,2,4,5,6,7
	Intravascular (Cardiac)							
	Trans-esoph.(Cardiac)							
	Intra-Cardiac							
Peripheral Vascular	Peripheral Vascular							
	Other (specify)							

N=new indication; P=previously cleared by FDA(K171034); 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 (Liver Only)

Concurrence of CDRH, Office of Device Evaluation(ODE)

Diagnostic Ultrasound Indications for Use Form

System: M7/M7T/M7 Premium/M7 Expert/M7 Super Diagnostic Ultrasound System
Transducer: L16-4Hs
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/ Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	P	P	P		P	P	Note1,2,4
	Intraoperative (specify)*	P	P	P		P	P	Note1,2,4
	Intraoperative (Neuro)							
	Laparoscopic							
	Pediatric	P	P	P		P	P	Note1,2,4
	Small organ(specify)**	P	P	P		P	P	Note1,2,4
	Neonatal Cephalic	P	P	P		P	P	Note1,2,4
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph.(non-Card.)							
	Musculo-skeletal Conventional	P	P	P		P	P	Note1,2,4
	Musculo-skeletal Superficial	P	P	P		P	P	Note1,2,4
	Intravascular							
	Other (specify)***							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph.(Cardiac)							
	Intra-Cardiac							
Peripheral Vascular	Peripheral Vascular	P	P	P		P	P	Note1,2,4
	Other (specify)							

N=new indication; P=previously cleared by FDA(K171034); 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 (Liver Only)

Concurrence of CDRH, Office of Device Evaluation(ODE)

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).

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2. Device Name: M7/M7T/M7 Premium/M7 Expert/M7 Super 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:

M7/M7T/M7 Premium/M7 Expert/M7 Super Diagnostic Ultrasound System is a general purpose, portable/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, Color M-Mode, Power/Dirpower Mode, TDI mode 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.

4. Intended Use:

The M7/M7T/M7 Premium/M7 Expert/M7 Super Diagnostic Ultrasound System is applicable for adults, pregnant women, pediatric patients and neonates. It is intended for use in gynecology, obstetric, abdominal, pediatric, small parts (breast, testes, thyroid), neonatal cephalic, transcranial, cardiac, transvaginal, transrectal, peripheral vascular, urology, orthopedic, and musculoskeletal(conventional and superficial), intraoperative and transesophageal(cardiac) exams.

5. Summary of Modifications

- **New Added Models:** M7 Expert, M7 Super, M7 Premium
- **New Added Transducers:** SP5-1s, L16-4Hs**,** C11-3s
- **New Added Needle-Guided Bracket:** NGB-018
- **Main Added Features:** Contrast Imaging, Elastography

6. Comparison with Predicate Devices:

M7/M7T/M7 Premium/M7 Expert/M7 Super Diagnostic Ultrasound System is comparable with and substantially equivalent to these predicate devices:

Predicate Device	Manufacturer	Model	510(k) Number
1.Primary predicate device	Mindray	M7	K131690
5.Reference device	Mindray	M9	K171034

They have the same technological characteristics, are comparable in key safety and

effectiveness features, and have the same intended uses and basic operating modes as the predicate devices.
The materials of probes and Needle-guided brackets of M7/M7T/M7 Premium/M7 Expert/M7 Super are the same to the probe of predicate device.
The acoustic power levels of M7/M7T/M7 Premium/M7 Expert/M7 Super are below the limits of FDA, which are the same as the predicated device M7(K131690).
The M7/M7T/M7 Premium/M7 Expert/M7 Super has the same imaging modes as the predicated devices.
All of the functions of M7/M7T/M7 Premium/M7 Expert/M7 Super are the same as the predicated devices.
The M7/M7T/M7 Premium/M7 Expert/M7 Super have similar tranducers with the predicated devices.

7. Non-clinical Tests:

M7/M7T/M7 Premium/M7 Expert/M7 Super 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. This device has been designed to meet the following standards:

- 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 3: 2007-03, medical electrical equipment - part 1-2: general requirements for basic safety and essential performance - collateral standard: electromagnetic compatibility - requirements and tests.
- 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.
- AAMI / ANSI / IEC 62304:2006, medical device software - software life cycle processes.

- ISO 14971 Second edition 2007-03-01, medical devices - application of risk management to medical devices.
- NEMA UD 2-2004 (R2009), acoustic output measurement standard for diagnostic ultrasound equipment revision 3.
- AAMI / ANSI / ISO 10993-1:2009/(R)2013, biological evaluation of medical devices - part 1: evaluation and testing within a risk management process.

8. 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 M7/M7T/M7 Premium/M7 Expert/M7 Super Diagnostic Ultrasound System is substantially equivalent with respect to safety and effectiveness to devices currently cleared for market.