



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 Guangdong  
P.R. CHINA

October 18, 2017

Re: K171579

Trade/Device Name: M6/M6T/M6 Exp/M6s/M6 Pro/M5 Exp/M55/M58 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 8, 2017  
Received: September 12, 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,

A handwritten signature in blue ink that reads "Michael D. O'Hara". The signature is written over a large, light blue, semi-transparent watermark of the letters "FDA". 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)

K171579

Device Name

M6/M6T/M6 Exp/M6s/M6 Pro/M5 Exp/M55/M58 Diagnostic Ultrasound System

Indications for Use (Describe)

The M6/M6T/M6 Exp/M6s/M6 Pro/M5 Exp/M55/M58 Diagnostic Ultrasound System is applicable for adults, pregnant women, pediatric patients and neonates. It is intended for use in fetal, abdominal, Intra-operative, pediatric, small organ (breast, thyroid, testes), neonatal cephalic, adult cephalic, trans-rectal, trans-vaginal, musculo-skeletal (conventional), musculo-skeletal (superficial), cardiac adult, cardiac pediatric, Trans-esoph.(Cardiac), 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: M6/M6T/M6 Exp/M6s/M6 Pro/M5 Exp/M55/M58 Diagnostic Ultrasound System

Transducer: /

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, 2,3,4,6,7
	Abdominal	N	N	N	N	N	N	N	Note 1, 2,3,4,5,6,7,9
	Intra-operative (Specify*)	N	N	N		N	N	N	Note 1, 2, 4,6,7
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	N	N	N	N	N	N	N	Note 1, 2,3, 4,5,6,7
	Small Organ (Specify**)	N	N	N		N	N	N	Note 1, 2, 4,6,7,8
	Neonatal Cephalic	N	N	N	N	N	N	N	Note 1, 2, 4,5,6,7
	Adult Cephalic	N	N	N	N	N	N	N	Note 1,2,4,5,6,7
	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	N	Note 1, 2, 4,5,6,7
	Musculo-skeletal (Superficial)	N	N	N		N	N	N	Note 1, 2, 4,6,7
Intravascular									
Cardiac	Cardiac Adult	N	N	N	N	N	N	N	Note 1,2,4,5,6,7
	Cardiac Pediatric	N	N	N	N	N	N	N	Note 1,2,4,5,6,7
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)	N	N	N	N	N	N	N	Note 1,2,5,6
	Intra-cardiac								
Peripheral vessel	Peripheral vessel	N	N	N		N	N	N	Note 1, 2, 4,6,7
	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

Note5: TDI

Note6: Color M

Note7: Biopsy Guidance

Note8: Strain Elastography

Note9: Contrast imaging (Liver Only)

Concurrence of CDRH, Office of Device Evaluation(ODE)

System: M6/M6T/M6 Exp/M6s/M6 Pro/M5 Exp/M55/M58 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 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	P	P	P		P	P	P	Note 1, 2, 4,6,7,9
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	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									
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
	Other (Specify***)								

N=new indication; P=previously cleared by FDA(K163690); 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)**

System: M6/M6T/M6 Exp/M6s/M6 Pro/M5 Exp/M55/M58 Diagnostic Ultrasound System

Transducer: 3C5s

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	P	P	P		P	P	P	Note 1,2,4,6,7,9
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	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									
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
	Other (Specify***)	P	P	P		P	P	P	Note 1,2,4,6,7

N=new indication; P=previously cleared by FDA(K163690, K102991); 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)**

System: M6/M6T/M6 Exp/M6s/M6 Pro/M5 Exp/M55/M58 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 Doppler	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	P	P	P		P	P	P	Note 1, 2, 4,6,7
	Musculo-skeletal Superficial	P	P	P		P	P	P	Note 1, 2, 4,6,7
Intravascular									
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-Cardiac								
Peripheral Vascular	Peripheral Vascular	P	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)**

System: M6/M6T/M6 Exp/M6s/M6 Pro/M5 Exp/M55/M58 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 Doppler	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
	Intra-operative (Specify*)								
	Intra-operative (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								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
Intravascular									
Cardiac	Cardiac Adult								
	Cardiac Pediatric	P	P	P		P	P	P	Note 1,2,4,6,7
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel	P	P	P		P	P	P	Note 1,2,4,6,7
	Other (Specify***)								

N=new indication; P=previously cleared by FDA(K152543, 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 etc.

\*\*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)**



System: M6/M6T/M6 Exp/M6s/M6 Pro/M5 Exp/M55/M58 Diagnostic Ultrasound System

Transducer: C6-2Gs

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	Note1,2,4,6,7
	Abdominal	P	P	P		P	P	P	Note1,2,4,6,7
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	P	Note1,2,4,6,7
	Small Organ (Specify**)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
Intravascular									
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(K152543, 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)**

System: M6/M6T/M6 Exp/M6s/M6 Pro/M5 Exp/M55/M58 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 Doppler	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)**	P	P	P		P	P	P	Note 1,2, 4,6,7
	Neonatal Cephalic	P	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	P	Note 1,2, 4,6,7
	Musculo-skeletal Superficial	P	P	P		P	P	P	Note 1,2, 4,6,7
Intravascular									
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-Cardiac								
Peripheral Vascular	Peripheral Vascular	P	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)

System: M6/M6T/M6 Exp/M6s/M6 Pro/M5 Exp/M55/M58 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 Doppler	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)**	P	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	P	Note 1,2, 4,6,7
	Musculo-skeletal Superficial	P	P	P		P	P	P	Note 1,2, 4,6,7
Intravascular									
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-Cardiac								
Peripheral Vascular	Peripheral Vascular	P	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)

System: M6/M6T/M6 Exp/M6s/M6 Pro/M5 Exp/M55/M58 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 Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intraoperative (specify)*								
	Intraoperative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	P	Note 1,2, 4,6,7
	Small organ(specify)**	P	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	P	Note 1,2, 4,6,7
	Musculo-skeletal Superficial	P	P	P		P	P	P	Note 1,2, 4,6,7
Intravascular									
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-Cardiac								
Peripheral Vascular	Peripheral Vascular	P	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)

System: M6/M6T/M6 Exp/M6s/M6 Pro/M5 Exp/M55/M58 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 Doppler	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
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	P	Note 1, 2, 4,6,7
	Small Organ (Specify**)	P	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	P	Note 1, 2, 4,6,7
Musculo-skeletal (Superficial)	P	P	P		P	P	P	Note 1, 2, 4,6,7	
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
	Other (Specify***)								

N=new indication; P=previously cleared by FDA(K152543, 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)**

System: M6/M6T/M6 Exp/M6s/M6 Pro/M5 Exp/M55/M58 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 Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intraoperative (specify)*								
	Intraoperative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	P	Note 1,2, 4,6,7
	Small organ(specify)**	P	P	P		P	P	P	Note 1,2, 4,6,7
	Neonatal Cephalic	P	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	P	Note 1,2, 4,6,7
	Musculo-skeletal Superficial	P	P	P		P	P	P	Note 1,2, 4,6,7
Intravascular									
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-Cardiac								
Peripheral Vascular	Peripheral Vascular	P	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)**

System: M6/M6T/M6 Exp/M6s/M6 Pro/M5 Exp/M55/M58 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 Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	P	Note 1, 2, 4,6,7
	Small Organ (Specify**)	P	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	P	Note 1, 2, 4,6,7
	Musculo-skeletal (Superficial)	P	P	P		P	P	P	Note 1, 2, 4,6,7
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
	Other (Specify***)								

N=new indication; P=previously cleared by FDA(K152543, 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)**

System: M6/M6T/M6 Exp/M6s/M6 Pro/M5 Exp/M55/M58 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 Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal	P	P	P		P	P	P	Note1,2,4,6,7
	Intraoperative (specify)*	P	P	P		P	P	P	Note1,2,4,6,7
	Intraoperative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	P	Note1,2,4,6,7
	Small organ(specify)**	P	P	P		P	P	P	Note1,2,4,6,7
	Neonatal Cephalic	P	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	P	Note1,2,4,6,7
	Musculo-skeletal Superficial	P	P	P		P	P	P	Note1,2,4,6,7
Intravascular									
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-Cardiac								
Peripheral Vascular	Peripheral Vascular	P	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)**



System: M6/M6T/M6 Exp/M6s/M6 Pro/M5 Exp/M55/M58 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 Doppler	Amplitude Doppler	Combined (specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal	P	P	P		P	P	P	Note1,2,4,6
	Intra-operative (Specify*)	P	P	P		P	P	P	Note1,2,4,6
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	P	Note1,2,4,6
	Small Organ (Specify**)	P	P	P		P	P	P	Note1,2,4,6
	Neonatal Cephalic	P	P	P		P	P	P	Note1,2,4,6
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	P	P	P		P	P	P	Note1,2,4,6
	Musculo-skeletal (Superficial)	P	P	P		P	P	P	Note1,2,4,6
Intravascular									
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel	P	P	P		P	P	P	Note1,2,4,6
	Other (Specify***)								

N=new indication; P=previously cleared by FDA(K170277, 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)**

System: M6/M6T/M6 Exp/M6s/M6 Pro/M5 Exp/M55/M58 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 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
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P	P	P	P	P	Note 1,2,4,5,6,7
	Small Organ (Specify**)								
	Neonatal Cephalic	P	P	P	P	P	P	P	Note 1,2,4,5,6,7
	Adult Cephalic	P	P	P	P	P	P	P	Note 1,2,4,5,6,7
	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
	Cardiac Pediatric	P	P	P	P	P	P	P	Note 1,2,4,5,6,7
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel								
	Other (Specify***)								

N=new indication; P=previously cleared by FDA(K163690); 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)**

System: M6/M6T/M6 Exp/M6s/M6 Pro/M5 Exp/M55/M58 Diagnostic Ultrasound System

Transducer: 2P2s

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
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P	P	P	P	P	Note 1,2,4,5,6,7
	Small Organ (Specify**)								
	Neonatal Cephalic	P	P	P	P	P	P	P	Note 1,2,4,5,6,7
	Adult Cephalic	P	P	P	P	P	P	P	Note 1,2,4,5,6,7
	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
	Cardiac Pediatric	P	P	P	P	P	P	P	Note 1,2,4,5,6,7
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel								
	Other (Specify***)								

N=new indication; P=previously cleared by FDA(K102991, K163690); 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)**

System: M6/M6T/M6 Exp/M6s/M6 Pro/M5 Exp/M55/M58 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 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
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P	P	P	P	P	Note 1,2,4,5,6
	Small Organ (Specify**)								
	Neonatal Cephalic	P	P	P	P	P	P	P	Note 1,2,4,5,6
	Adult Cephalic	P	P	P	P	P	P	P	Note 1,2,4,5,6
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	P	P	P	P	P	P	P	Note 1,2,4,5,6
Musculo-skeletal (Superficial)									
Intravascular									
Cardiac	Cardiac Adult	P	P	P	P	P	P	P	Note 1,2,4,5,6
	Cardiac Pediatric	P	P	P	P	P	P	P	Note 1,2,4,5,6
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel								
	Other (Specify***)								

N=new indication; P=previously cleared by FDA(K131690, K163690); 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)**

System: M6/M6T/M6 Exp/M6s/M6 Pro/M5 Exp/M55/M58 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 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
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P	P	P	P	P	Note 1,2,4,5,6
	Small Organ (Specify**)								
	Neonatal Cephalic	P	P	P	P	P	P	P	Note 1,2,4,5,6
	Adult Cephalic	P	P	P	P	P	P	P	Note 1,2,4,5,6
	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
	Cardiac Pediatric	P	P	P	P	P	P	P	Note 1,2,4,5,6
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel								
	Other (Specify***)								

N=new indication; P=previously cleared by FDA(K131690, K163690); 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)**

System: M6/M6T/M6 Exp/M6s/M6 Pro/M5 Exp/M55/M58 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 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								
	Intraoperative (specify)*								
	Intraoperative (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 Vascular	Peripheral Vascular						P		
	Other (specify)***	P	P	P		P	P	P	Note 1, 2, 4,6,7

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)**

System: M6/M6T/M6 Exp/M6s/M6 Pro/M5 Exp/M55/M58 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 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								
	Intraoperative (specify)*								
	Intraoperative (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 Vascular	Peripheral Vascular								
	Other (specify)***	P	P	P		P	P	P	Note 1, 2, 4,6,7

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)**

System: M6/M6T/M6 Exp/M6s/M6 Pro/M5 Exp/M55/M58 Diagnostic Ultrasound System

Transducer: 6CV1s

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(K102991, 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)**



System: M6/M6T/M6 Exp/M6s/M6 Pro/M5 Exp/M55/M58 Diagnostic Ultrasound System

Transducer: 6LB7s

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**)									
	Neonatal Cephalic									
	Adult Cephalic									
	Trans-rectal	P	P	P			P	P	P	Note 2,4,6,7
	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***)	P	P	P			P	P	P	Note 2,4,6,7

N=new indication; P=previously cleared by FDA(K102991, 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)**

System: M6/M6T/M6 Exp/M6s/M6 Pro/M5 Exp/M55/M58 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 Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	P	P	P		P	P	P	Note 1,3,4,6
	Abdominal	P	P	P		P	P	P	Note 1,3,4,6
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	P	Note 1,3,4,6
	Small Organ (Specify**)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
Intravascular									
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(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)**

System: M6/M6T/M6 Exp/M6s/M6 Pro/M5 Exp/M55/M58 Diagnostic Ultrasound System

Transducer: D7-2s

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 Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	P	P	P		P	P	P	Note 1, 3, 4, 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(K163690); 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 etc.

\*\*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)**

System: M6/M6T/M6 Exp/M6s/M6 Pro/M5 Exp/M55/M58 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 Doppler	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									
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)**

System: M6/M6T/M6 Exp/M6s/M6 Pro/M5 Exp/M55/M58 Diagnostic Ultrasound System

Transducer: CW5s

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					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									
Cardiac	Cardiac Adult					P			
	Cardiac Pediatric					P			
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel								
	Other (Specify***)								

N=new indication; P=previously cleared by FDA(K170277); 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)**

System: M6/M6T/M6 Exp/M6s/M6 Pro/M5 Exp/M55/M58 Diagnostic Ultrasound System

Transducer: DE11-3s

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 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(K163690); 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)**

System: M6/M6T/M6 Exp/M6s/M6 Pro/M5 Exp/M55/M58 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 Doppler	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									
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph.(Cardiac)	P	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)**

# 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:**

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**Date Prepared:** May 19, 2017

**2. Device Name:** M6/M6T/M6 EXP/M6S/M6 PRO/M5 EXP/M55/M58 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:**

M6/M6T/M6 EXP/M6S/M6 PRO/M5 EXP/M55/M58 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 M6/M6T/M6 Exp/M6s/M6 Pro/M5 Exp/M55/M58 Diagnostic Ultrasound System is applicable for adults, pregnant women, pediatric patients and neonates. It is intended for use in fetal, abdominal, Intra-operative, pediatric, small organ (breast, thyroid, testes), neonatal cephalic, adult cephalic, trans-rectal, trans-vaginal, musculo-skeletal (conventional), musculo-skeletal (superficial), cardiac adult, cardiac pediatric, Trans-esoph. (Cardiac), peripheral vessel and urology exams.

#### **5. Comparison with Predicate Devices:**

M6/M6T/M6 Exp/M6s/M6 Pro/M5 Exp/M55/M58 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
2.Reference device	Mindray	M5	K102991
3.Reference device	Mindray	DC-70	K163690
4.Reference device	Mindray	DC-8	K170277
5.Reference device	Mindray	M9	K152543

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 M6/M6T/M6 Exp/M6s/M6 Pro/M5 Exp/M55/M58 are the same to the probe of predicate device.

The acoustic power levels of M6/M6T/M6 Exp/M6s/M6 Pro/M5 Exp/M55/M58 are below the limits of FDA, which are the same as the predicated device M7(K131690).

The M6/M6T/M6 Exp/M6s/M6 Pro/M5 Exp/M55/M58 has the same imaging modes as the predicated devices.

All of the functions of M6/M6T/M6 Exp/M6s/M6 Pro/M5 Exp/M55/M58 are the same as the predicated devices.

The M6/M6T/M6 Exp/M6s/M6 Pro/M5 Exp/M55/M58 have similar transducers with the predicated devices.

#### **6. Non-clinical Tests:**

M6/M6T/M6 Exp/M6s/M6 Pro/M5 Exp/M55/M58 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.

### **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 M6/M6T/M6 Exp/M6s/M6 Pro/M5 Exp/M55/M58 Diagnostic Ultrasound System is substantially equivalent with respect to safety and effectiveness to devices currently cleared for market.