



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

July 30th, 2018

Re: K180912

Trade/Device Name: TE7/TE5 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: July 4, 2018

Received: July 9, 2018

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.

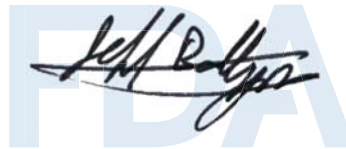
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,



for
Robert A. 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)

K180912

Device Name

TE7/TE5 Diagnostic Ultrasound System

Indications for Use (Describe)

TE7/TE5 Diagnostic Ultrasound System is applicable for adults, pregnant women, pediatric patients and neonates. It is intended for use in fetal, abdominal, Intra-operative(abdominal, thoracic, and vascular), Pediatric ,small organ(breast, thyroid, testes), neonatal and adult cephalic, trans-esoph. (Cardiac), trans-rectal, trans-vaginal, musculo-skeletal (conventional, superficial), urology, Peripheral vessel, Adult and Pediatric cardiac, ophthalmic 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: TE7/TE5 Diagnostic Ultrasound System

Transducer: N/A

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

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

N=new indication; P=previously cleared by FDA (K161525) ; 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. The feature does not use contrast agents.

Note2: Biopsy Guidance

Note3: Contrast imaging (Contrast agent for LVO)

Note4: TDI

Note5: Color M

Note6: Smart 3D

Note7: Contrast imaging (Contrast agent for Liver)

Note8: eSpacial Navi

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Concurrence of CDRH, Office of Device Evaluation(ODE)

C11-3s

System: TE7/TE5 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 1,2,5
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	P	Note 1,2,5
	Small Organ (Specify**)								
	Neonatal Cephalic	P	P	P		P	P	P	Note 1,2,5
	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 1,2,5
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel	P	P	P		P	P	P	Note 1,2,5
	Other (Specify***)								

N=new indication; P=previously cleared by FDA (K161525) ; 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. The feature does not use contrast agents.

Note2: Biopsy Guidance

Note3: Contrast imaging (Contrast agent for LVO)

Note4: TDI

Note5: Color M

Note6: Smart 3D

Note7: Contrast imaging (Contrast agent for Liver)

Note8: eSpacial Navi

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Concurrence of CDRH, Office of Device Evaluation(ODE)

C5-2s

System: TE7/TE5 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 1,2,5
	Abdominal	P	P	P		P	P	P	Note 1,2,5,7
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	P	Note 1,2,5
	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 1,2,5
	Other (Specify***)								
N=new indication; P=previously cleared by FDA (K161525) ; 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. The feature does not use contrast agents.									
Note2: Biopsy Guidance									
Note3: Contrast imaging (Contrast agent for LVO)									
Note4: TDI									
Note5: Color M									
Note6: Smart 3D									
Note7: Contrast imaging (Contrast agent for Liver)									
Note8: eSpacial Navi									
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Concurrence of CDRH, Office of Device Evaluation(ODE)									

P7-3Ts

System: TE7/TE5 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								
	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)	P	P	P	P	P	P	P	Note 1,4,5
	Intra-cardiac								
Peripheral vessel	Peripheral vessel								
	Other (Specify***)								
N=new indication; P=previously cleared by FDA (K161525) ; 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. The feature does not use contrast agents.									
Note2: Biopsy Guidance									
Note3: Contrast imaging (Contrast agent for LVO)									
Note4: TDI									
Note5: Color M									
Note6: Smart 3D									
Note7: Contrast imaging (Contrast agent for Liver)									
Note8: eSpacial Navi									
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Concurrence of CDRH, Office of Device Evaluation(ODE)									

L12-4s

System: TE7/TE5 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	N	N	N		N	N	N	Note 1,2,6
Fetal Imaging & Other	Fetal								
	Abdominal	P	P	P		P	P	P	Note 1,2,6
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	P	Note 1,2,6
	Small Organ (Specify**)	P	P	P		P	P	P	Note 1,2,6
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	P	P	P		P	P	P	Note 1,2,6
Musculo-skeletal (Superficial)	P	P	P		P	P	P	Note 1,2,6	
Intravascular									
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel	P	P	P		P	P	P	Note 1,2,6
	Other (Specify***)								
N=new indication; P=previously cleared by FDA (K161525) ; 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. The feature does not use contrast agents.									
Note2: Biopsy Guidance									
Note3: Contrast imaging (Contrast agent for LVO)									
Note4: TDI									
Note5: Color M									
Note6: Smart 3D									
Note7: Contrast imaging (Contrast agent for Liver)									
Note8: eSpacial Navi									
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Concurrence of CDRH, Office of Device Evaluation(ODE)									

L7-3s

System: TE7/TE5 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
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	P	Note 1,2
	Small Organ (Specify**)	P	P	P		P	P	P	Note 1,2
	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
Musculo-skeletal (Superficial)	P	P	P		P	P	P	Note 1,2	
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
	Other (Specify***)								
N=new indication; P=previously cleared by FDA (K161525) ; 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. The feature does not use contrast agents.									
Note2: Biopsy Guidance									
Note3: Contrast imaging (Contrast agent for LVO)									
Note4: TDI									
Note5: Color M									
Note6: Smart 3D									
Note7: Contrast imaging (Contrast agent for Liver)									
Note8: eSpacial Navi									
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Concurrence of CDRH, Office of Device Evaluation(ODE)									

L14-6s

System: TE7/TE5 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								
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	P	Note 1,2
	Small Organ (Specify**)	P	P	P		P	P	P	Note 1,2
	Neonatal Cephalic	P	P	P		P	P	P	Note 1,2
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	P	P	P		P	P	P	Note 1,2
	Musculo-skeletal (Superficial)	P	P	P		P	P	P	Note 1,2
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
	Other (Specify***)								
N=new indication; P=previously cleared by FDA (K161525) ; 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. The feature does not use contrast agents.									
Note2: Biopsy Guidance									
Note3: Contrast imaging (Contrast agent for LVO)									
Note4: TDI									
Note5: Color M									
Note6: Smart 3D									
Note7: Contrast imaging (Contrast agent for Liver)									
Note8: eSpacial Navi									
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Concurrence of CDRH, Office of Device Evaluation(ODE)									

L14-6Ns

System: TE7/TE5 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	N	N	N		N	N	N	Note 1,2,6
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	P	Note 1,2,6
	Small Organ (Specify**)	P	P	P		P	P	P	Note 1,2,6
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	P	P	P		P	P	P	Note 1,2,6
Musculo-skeletal (Superficial)	P	P	P		P	P	P	Note 1,2,6	
Intravascular									
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel	P	P	P		P	P	P	Note 1,2,6
	Other (Specify***)								
N=new indication; P=previously cleared by FDA (K161525) ; 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. The feature does not use contrast agents.									
Note2: Biopsy Guidance									
Note3: Contrast imaging (Contrast agent for LVO)									
Note4: TDI									
Note5: Color M									
Note6: Smart 3D									
Note7: Contrast imaging (Contrast agent for Liver)									
Note8: eSpacial Navi									
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Concurrence of CDRH, Office of Device Evaluation(ODE)									

P4-2s

System: TE7/TE5 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	N	N	N		N	N	N	Note 1,2,5
	Abdominal	P	P	P	P	P	P	P	Note 1,2,5
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P	P	P	P	P	Note 1,2,5
	Small Organ (Specify**)								
	Neonatal Cephalic	P	P	P	P	P	P	P	Note 1,2,5
	Adult Cephalic	P	P	P	P	P	P	P	Note 1,2,5
	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, 2,3,4,5
	Cardiac Pediatric	P	P	P	P	P	P	P	Note 1,2,4,5
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel								
	Other (Specify***)								
N=new indication; P=previously cleared by FDA (K161525) ; 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. The feature does not use contrast agents.									
Note2: Biopsy Guidance									
Note3: Contrast imaging (Contrast agent for LVO)									
Note4: TDI									
Note5: Color M									
Note6: Smart 3D									
Note7: Contrast imaging (Contrast agent for Liver)									
Note8: eSpacial Navi									
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Concurrence of CDRH, Office of Device Evaluation(ODE)									

V11-3Ws

System: TE7/TE5 Diagnostic Ultrasound System

Transducer: V11-3Ws

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 1,2,5
	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 1,2,5
	Trans-vaginal	P	P	P		P	P	P	Note 1,2,5
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Cardiac	Musculo-skeletal (Conventional)							
Musculo-skeletal (Superficial)									
Intravascular									
Cardiac Adult									
Cardiac Pediatric									
Peripheral vessel	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel								
	Other (Specify***)	P	P	P		P	P	P	Note 1,2,5
N=new indication; P=previously cleared by FDA (K161525) ; 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. The feature does not use contrast agents.									
Note2: Biopsy Guidance									
Note3: Contrast imaging (Contrast agent for LVO)									
Note4: TDI									
Note5: Color M									
Note6: Smart 3D									
Note7: Contrast imaging (Contrast agent for Liver)									
Note8: eSpacial Navi									
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Concurrence of CDRH, Office of Device Evaluation(ODE)									

7LT4s

System: TE7/TE5 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	Note 1,2
	Intra-operative (Specify*)	P	P	P		P	P	P	Note 1,2
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	P	Note 1,2
	Small Organ (Specify**)	P	P	P		P	P	P	Note 1,2
	Neonatal Cephalic	P	P	P		P	P	P	Note 1,2
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	P	P	P		P	P	P	Note 1,2
Musculo-skeletal (Superficial)	P	P	P		P	P	P	Note 1,2	
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
	Other (Specify***)								
N=new indication; P=previously cleared by FDA (K161525); 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. The feature does not use contrast agents.									
Note2: Biopsy Guidance									
Note3: Contrast imaging (Contrast agent for LVO)									
Note4: TDI									
Note5: Color M									
Note6: Smart 3D									
Note7: Contrast imaging (Contrast agent for Liver)									
Note8: eSpacial Navi									
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Concurrence of CDRH, Office of Device Evaluation(ODE)									

L14-5sp

System: TE7/TE5 Diagnostic Ultrasound System

Transducer: L14-5sp

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
	Intra-operative (Specify*)	P	P	P		P	P	P	Note 1
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	P	Note 1
	Small Organ (Specify**)	P	P	P		P	P	P	Note 1
	Neonatal Cephalic	P	P	P		P	P	P	Note 1
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	P	P	P		P	P	P	Note 1
Musculo-skeletal (Superficial)	P	P	P		P	P	P	Note 1	
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
	Other (Specify***)								
N=new indication; P=previously cleared by FDA (K161525); 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. The feature does not use contrast agents.									
Note2: Biopsy Guidance									
Note3: Contrast imaging (Contrast agent for LVO)									
Note4: TDI									
Note5: Color M									
Note6: Smart 3D									
Note7: Contrast imaging (Contrast agent for Liver)									
Note8: eSpacial Navi									
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Concurrence of CDRH, Office of Device Evaluation(ODE)									

P10-4s

System: TE7/TE5 Diagnostic Ultrasound System

Transducer: P10-4s

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 1,5
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P	P	P	P	P	Note 1,5
	Small Organ (Specify**)								
	Neonatal Cephalic	P	P	P	P	P	P	P	Note 1,5
	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	P	Note 1, 4,5
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
Peripheral vessel	Intra-cardiac								
	Peripheral vessel								
	Other (Specify***)								
N=new indication; P=previously cleared by FDA (K161525); 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. The feature does not use contrast agents.									
Note2: Biopsy Guidance									
Note3: Contrast imaging (Contrast agent for LVO)									
Note4: TDI									
Note5: Color M									
Note6: Smart 3D									
Note7: Contrast imaging (Contrast agent for Liver)									
Note8: eSpacial Navi									
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Concurrence of CDRH, Office of Device Evaluation(ODE)									

L20-5s

System: TE7/TE5 Diagnostic Ultrasound System

Transducer: L20-5s

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	N	N	N		N	N	N	Note 1
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify**)	P	P	P		P	P	P	Note 1
	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
Musculo-skeletal (Superficial)	P	P	P		P	P	P	Note 1	
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
	Other (Specify***)								
N=new indication; P=previously cleared by FDA (K161525) ; 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. The feature does not use contrast agents.									
Note2: Biopsy Guidance									
Note3: Contrast imaging (Contrast agent for LVO)									
Note4: TDI									
Note5: Color M									
Note6: Smart 3D									
Note7: Contrast imaging (Contrast agent for Liver)									
Note8: eSpacial Navi									
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Concurrence of CDRH, Office of Device Evaluation(ODE)									

SC6-1s

System: TE7/TE5 Diagnostic Ultrasound System

Transducer: SC6-1s

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 Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	P	P	P		P	P	P	Note 1,2,5
	Abdominal	P	P	P		P	P	P	Note 1,2,5
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	P	Note 1,2,5
	Small Organ (Specify**)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	P	P	P		P	P	P	Note 1,2,5
	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 1,2,5
	Other (Specify***)								
N=new indication; P=previously cleared by FDA (K161525) ; 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. The feature does not use contrast agents.									
Note2: Biopsy Guidance									
Note3: Contrast imaging (Contrast agent for LVO)									
Note4: TDI									
Note5: Color M									
Note6: Smart 3D									
Note7: Contrast imaging (Contrast agent for Liver)									
Note8: eSpacial Navi									
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Concurrence of CDRH, Office of Device Evaluation(ODE)									

SP5-1s

System: TE7/TE5 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 Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	N	N	N	N	N	N	N	Note 1,2,5
	Abdominal	P	P	P	P	P	P	P	Note 1,2,5
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P	P	P	P	P	Note 1,2,5
	Small Organ (Specify**)								
	Neonatal Cephalic	P	P	P	P	P	P	P	Note 1,2,5
	Adult Cephalic	P	P	P	P	P	P	P	Note 1,2,5
	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 1,2,3,4,5
	Cardiac Pediatric	P	P	P	P	P	P	P	Note 1,2,4,5
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel								
	Other (Specify***)								
N=new indication; P=previously cleared by FDA (K161525) ; 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. The feature does not use contrast agents.									
Note2: Biopsy Guidance									
Note3: Contrast imaging (Contrast agent for LVO)									
Note4: TDI									
Note5: Color M									
Note6: Smart 3D									
Note7: Contrast imaging (Contrast agent for Liver)									
Note8: eSpacial Navi									
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Concurrence of CDRH, Office of Device Evaluation(ODE)									

6CV1s

System: TE7/TE5 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 1,2,5
	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 1,2,5
	Trans-vaginal	P	P	P		P	P	P	Note 1,2,5
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	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 1,2,5
N=new indication; P=previously cleared by FDA (K161525); 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. The feature does not use contrast agents. Note2: Biopsy Guidance Note3: Contrast imaging (Contrast agent for LVO) Note4: TDI Note5: Color M Note6: Smart 3D Note7: Contrast imaging (Contrast agent for Liver) Note8: eSpacial Navi (PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE NEEDED) Concurrence of CDRH, Office of Device Evaluation(ODE)									

7L4s

System: TE7/TE5 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
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	P	Note 1, 2
	Small Organ (Specify**)	P	P	P		P	P	P	Note 1, 2
	Neonatal Cephalic	P	P	P		P	P	P	Note 1, 2
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Cardiac	Musculo-skeletal (Conventional)	P	P	P		P	P	P
Musculo-skeletal (Superficial)		P	P	P		P	P	P	Note 1, 2
Intravascular									
Cardiac Adult									
Cardiac Pediatric									
Peripheral vessel	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel	P	P	P		P	P	P	Note 1, 2
	Other (Specify***)								

N=new indication; P=previously cleared by FDA (K161525) ; 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. The feature does not use contrast agents.

Note2: Biopsy Guidance

Note3: Contrast imaging (Contrast agent for LVO)

Note4: TDI

Note5: Color M

Note6: Smart 3D

Note7: Contrast imaging (Contrast agent for Liver)

Note8: eSpacial Navi

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Concurrence of CDRH, Office of Device Evaluation(ODE)

P7-3s

System: TE7/TE5 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 1,5
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P	P	P	P	P	Note 1,5
	Small Organ (Specify**)								
	Neonatal Cephalic	P	P	P	P	P	P	P	Note 1,5
	Adult Cephalic	P	P	P	P	P	P	P	Note 1,5
	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 1,4,5
	Cardiac Pediatric	P	P	P	P	P	P	P	Note 1,4,5
	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. The feature does not use contrast agents.									
Note2: Biopsy Guidance									
Note3: Contrast imaging (Contrast agent for LVO)									
Note4: TDI									
Note5: Color M									
Note6: Smart 3D									
Note7: Contrast imaging (Contrast agent for Liver)									
Note8: eSpacial Navi									
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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)									

C5-1s

System: TE7/TE5 Diagnostic Ultrasound System

Transducer: C5-1s

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 Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	P	P	P		P	P	P	Note 1,2,5
	Abdominal	P	P	P		P	P	P	Note 1,2,5,7
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	P	Note 1,2,5
	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 1,2,5
	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. The feature does not use contrast agents.									
Note2: Biopsy Guidance									
Note3: Contrast imaging (Contrast agent for LVO)									
Note4: TDI									
Note5: Color M									
Note6: Smart 3D									
Note7: Contrast imaging (Contrast agent for Liver)									
Note8: eSpacial Navi									
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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)									

C4-1s

System: TE7/TE5 Diagnostic Ultrasound System

Transducer: C4-1s

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 Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	P	P	P	P	P	P	P	Note 1,2,5
	Abdominal	P	P	P	P	P	P	P	Note 1,2,5,7
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	P	Note 1,2,5
	Small Organ (Specify**)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	P	P	P		P	P	P	Note 1,2,5
	Musculo-skeletal (Superficial)								
Intravascular									
Cardiac	Cardiac Adult	P	P	P	P	P	P	P	Note 1,2,5
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel								
	Other (Specify***)								
N=new indication; P=previously cleared by FDA(K171233); E=added under Appendix E									
Additional comments: Combined modes--B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.									
*Intraoperative includes abdominal, thoracic, and vascular									
**Small organ-breast, thyroid, testes.									
***Other use includes Urology.									
Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.									
Note2: Biopsy Guidance									
Note3: Contrast imaging (Contrast agent for LVO)									
Note4: TDI									
Note5: Color M									
Note6: Smart 3D									
Note7: Contrast imaging (Contrast agent for Liver)									
Note8: eSpacial Navi									
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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)									

L9-3s

System: TE7/TE5 Diagnostic Ultrasound System

Transducer: L9-3s

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
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	P	Note 1,2
	Small Organ (Specify**)	P	P	P		P	P	P	Note 1,2
	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
	Musculo-skeletal (Superficial)	P	P	P		P	P	P	Note 1,2
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
	Other (Specify***)								
N=new indication; P=previously cleared by FDA(K171233); E=added under Appendix E									
Additional comments: Combined modes--B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.									
*Intraoperative includes abdominal, thoracic, and vascular									
**Small organ-breast, thyroid, testes.									
***Other use includes Urology.									
Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.									
Note2: Biopsy Guidance									
Note3: Contrast imaging (Contrast agent for LVO)									
Note4: TDI									
Note5: Color M									
Note6: Smart 3D									
Note7: Contrast imaging (Contrast agent for Liver)									
Note8: eSpacial Navi									
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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)									

L11-3VNs

System: TE7/TE5 Diagnostic Ultrasound System

Transducer: L11-3VNs

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 1,2,8
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	P	Note 1,2,8
	Small Organ (Specify**)	P	P	P		P	P	P	Note 1,2,8
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	P	P	P		P	P	P	Note 1,2,8
	Musculo-skeletal (Superficial)	P	P	P		P	P	P	Note 1,2,8
Intravascular									
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel	P	P	P		P	P	P	Note 1,2,8
	Other (Specify***)								
N=new indication; P=previously cleared by FDA(171233); 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. The feature does not use contrast agents.									
Note2: Biopsy Guidance									
Note3: Contrast imaging (Contrast agent for LVO)									
Note4: TDI									
Note5: Color M									
Note6: Smart 3D									
Note7: Contrast imaging (Contrast agent for Liver)									
Note8: eSpacial Navi									
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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)									

L12-3RCs

System: TE7/TE5 Diagnostic Ultrasound System

Transducer: L12-3RC

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 1,2,8
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	P	Note 1,2,8
	Small Organ (Specify**)	P	P	P		P	P	P	Note 1,2,8
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	P	P	P		P	P	P	Note 1,2,8
	Musculo-skeletal (Superficial)	P	P	P		P	P	P	Note 1,2,8
Intravascular									
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel	P	P	P		P	P	P	Note 1,2,8
	Other (Specify***)								
N=new indication; P=previously cleared by FDA(K171233); E=added under Appendix E									
Additional comments: Combined modes--B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.									
*Intraoperative includes abdominal, thoracic, and vascular etc.									
**Small organ-breast, thyroid, testes.									
***Other use includes Urology.									
Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.									
Note2: Biopsy Guidance									
Note3: Contrast imaging (Contrast agent for LVO)									
Note4: TDI									
Note5: Color M									
Note6: Smart 3D									
Note7: Contrast imaging (Contrast agent for Liver)									
Note8: eSpacial Navi									
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE NEEDED)									
Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)									

L14-5Ws

System: TE7/TE5 Diagnostic Ultrasound System

Transducer: L14-5Ws

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
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	P	Note 1,2
	Small Organ (Specify**)	P	P	P		P	P	P	Note 1,2
	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
	Musculo-skeletal (Superficial)	P	P	P		P	P	P	Note 1,2
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
	Other (Specify***)								
N=new indication; P=previously cleared by FDA(K171233); E=added under Appendix E									
Additional comments: Combined modes--B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.									
*Intraoperative includes abdominal, thoracic, and vascular etc.									
**Small organ-breast, thyroid, testes.									
***Other use includes Urology.									
Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.									
Note2: Biopsy Guidance									
Note3: Contrast imaging (Contrast agent for LVO)									
Note4: TDI									
Note5: Color M									
Note6: Smart 3D									
Note7: Contrast imaging (Contrast agent for Liver)									
Note8: eSpacial Navi									
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE NEEDED)									
Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)									

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92(c).

1. Submitter:

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Date Prepared: March 26, 2018

2. Device Name: TE7 Diagnostic Ultrasound System, TE5 Diagnostic Ultrasound System

Classification

Regulatory Class: II

Review Category: Tier II

21 CFR 892.1550 Ultrasonic Pulsed Doppler Imaging System (IYN)

21 CFR 892.1560 Ultrasonic Pulsed Echo Imaging System (IYO)

21 CFR 892.1570 Diagnostic Ultrasound Transducer (ITX)

3. Device Description:

TE7/TE5 is a software controlled, ultrasonic diagnostic system. Its function is to acquire and display ultrasound data in B-Mode, M-Mode, PW-Mode, CW-mode, Color-Mode, Power/Dirpower Mode, THI, LVO, Color M, Smart 3D, TDI or the combined mode (i.e. B/M-Mode, B/PW-mode, B/PW/Color)..

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

4. Intended Use:

TE7/TE5 Diagnostic Ultrasound System is applicable for adults, pregnant women, pediatric patients and neonates. It is intended for use in fetal, abdominal, Intra-operative(abdominal, thoracic, and vascular), Pediatric ,small organ(breast, thyroid, testes), neonatal and adult cephalic, trans-esoph. (Cardiac), trans-rectal, trans-vaginal, musculo-skeletal(conventional, superficial), urology, Peripheral vessel, Adult and Pediatric cardiac, ophthalmic exams.

5. Summary of Modifications

This submission device is a modification to TE7/TE5 Diagnostic Ultrasound System previously cleared in K161525.

The following is a brief overview of the modifications.

■ **Newly added transducers:**

C5-1s, L9-3s, L11-3VNs, C4-1s, L12-3RCs, L14-5Ws, P7-3s

■ **New Added Needle-Guided Bracket:**

NGB-022, NGB-034, NGB-035, NGB-036

■ **Newly added Features:**

eSpacial Navi

Auto EF

Exam mode of Ophthalmic for Liner probes L14-6Ns、 L12-4s、 L20-5s

Exam mode of OB for Phased probes SP5-1s、 P4-2s

■ **Add the Contrast Imaging(for liver) Function to C5-1s、 C4-1s and C5-2s**

All of the above modifications and newly added features have been compared with the

predicate devices. The results show that these modifications and newly added features are substantially equivalent to the predicate devices.

6. Comparison with Predicate Devices:

TE7/TE5 Diagnostic Ultrasound System is comparable with and substantially equivalent to these predicate devices:

Predicate Device	Manufacturer	Model	510(k) Control Number
1.Primary predicate device	Mindray	TE7	K161525
2. Reference device	Zonare	ZS3	K171891
3.Reference device	Mindray	DC-70	K163690
4.Reference device	eZono AG	eZono 4000	K140254
5.Reference device	Mindray	Resona 7	K171233
6.Reference device	Mindray	M9	K171034

TE7/TE5 Diagnostic Ultrasound System employs the same technology as the predicate devices. All systems transmit ultrasonic energy into patients, then perform post processing of received echoes to generate onscreen display of anatomic structures and fluid flow within the body. All systems allow for specialized measurements of structures and flow, and calculations. The subject device also has the same intended uses and basic operating modes as the predicate devices.

- Subject device TE7/TE5 has the same intended uses as the predicated device TE7/TE5 (K161525)
- The materials of probes and Needle-guided brackets of TE7/TE5 are the same to the probe of predicate device.
- The acoustic power levels of TE7/TE5 are below the limits of FDA, which is the same as the predicated device TE7/TE5 (K161525) and ZS3(K171891).
- TE7/TE5 is designed in compliance with the FDA recognized electrical and physical safety standards, which are the same as the predicated device TE7/TE5 (K161525).

7. Non-clinical Tests:

TE7/TE5 Diagnostic Ultrasound System has been evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness as well as thermal, electrical and mechanical safety, and has been found to conform with applicable medical safety standards.

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

- AAMI / ANSI ES60601-1:2005/(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.

These non-clinical tests relied on in this premarket notification submission can support the determination of substantial equivalence of the subject device.

8. Clinical Studies

Not applicable. The subject of this submission, TE7/TE5 Diagnostic Ultrasound System, does not require clinical studies to support substantial equivalence.

Conclusion:

Intended uses and other key features are consistent with traditional clinical practices, FDA guidelines and established methods of patient examination. The design, development and quality process of the manufacturer confirms with 21 CFR 820, ISO 9001 and ISO 13485 quality systems. The device conforms to applicable medical device safety standards. Therefore, the TE7/TE5 Diagnostic Ultrasound System is substantially equivalent with respect to safety and effectiveness to devices currently cleared for market.