



November 14, 2018

Shenzhen Mindray Bio-medical Electronics Co., LTD
Jiang Xiaoyong
Engineer of Technical Regulation
Keji 12th Road South, Hi-tech Industrial Park
Shenzhen, Guangdong 518057
CHINA

Re: K182603

Trade/Device Name: Z6 Diagnostic Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic Pulsed Doppler Imaging System
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: August 31, 2018
Received: September 21, 2018

Dear Jiang Xiaoyong:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see <https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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,

A handwritten signature in black ink, appearing to read "Rob 2. Ochs", is written over a large, light blue, semi-transparent "FDA" watermark.

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

Enclosure

Indications for Use

510(k) Number (if known)

K182603

Device Name

Z6 Diagnostic Ultrasound System

Indications for Use (Describe)

The Z6 Diagnostic Ultrasound System is applicable for adults, pregnant women, pediatric patients and neonates. It is intended for use in fetal, abdominal, pediatric, small organ(breast, thyroid, testes), neonatal and adult cephalic, trans-rectal, trans-vaginal, musculo-skeletal(conventional, superficial), adult and pediatric cardiac, peripheral vessel, intra-operative(abdominal, thoracic, and vascular) 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: Z6 Diagnostic Ultrasound System

Transducer: N/A

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

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

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: Biopsy Guidance

Note 3: iScape

Note 4: TDI

Note5: Color M

Note6: Smart3D

Note7: 4D(Real-time 3D)

Note8: Strain Elastography

Note 9: Contrast imaging (Contrast agent for Liver)

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

System: Z6 Diagnostic Ultrasound System

Transducer: 3C5P

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

Clinical Application		Mode of Operation							
General (Track 1)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	P	P	P		P	P	P	Note 1,2,5,6
	Abdominal	P	P	P		P	P	P	Note 1,2,5,6,9
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	P	Note 1,2,5,6
	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 1,2,5,6
	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 1,2,5,6
	Other (Specify***)								
N=new indication; P=previously cleared by FDA(K122010); 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: Biopsy Guidance									
Note 3: iScape									
Note 4: TDI									
Note5: Color M									
Note6: Smart3D									
Note7: 4D(Real-time 3D)									
Note8: Strain Elastography									
Note 9: Contrast imaging (Contrast agent for Liver)									
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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)									

System: Z6 Diagnostic Ultrasound System

Transducer: 6C2P

Intended Use:

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

Clinical Application		Mode of Operation							
General (Track 1)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal	P	P	P		P	P	P	Note 1,2,5,6
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	P	Note 1,2,5,6
	Small Organ (Specify**)								
	Neonatal Cephalic	P	P	P		P	P	P	Note 1,2,5,6
	Adult Cephalic	P	P	P		P	P	P	Note 1,2,5,6
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Cardiac	Intravascular							
Cardiac Adult									
Cardiac Pediatric									
Intravascular (Cardiac)									
Trans-esoph. (Cardiac)									
Peripheral vessel	Intra-cardiac								
	Peripheral vessel								
	Other (Specify***)								
N=new indication; P=previously cleared by FDA(K122010); 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: Biopsy Guidance									
Note 3: iScape									
Note 4: TDI									
Note5: Color M									
Note6: Smart3D									
Note7: 4D(Real-time 3D)									
Note8: Strain Elastography									
Note 9: Contrast imaging (Contrast agent for Liver)									
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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)									

System: Z6 Diagnostic Ultrasound System

Transducer: 6CV1P

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

Clinical Application		Mode of Operation							
General (Track 1)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	P	P	P		P	P	P	Note 1,2,5,6
	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 1,2,5,6
	Trans-vaginal	P	P	P		P	P	P	Note 1,2,5,6
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
Cardiac	Intravascular								
	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
Peripheral vessel	Intra-cardiac								
	Peripheral vessel								
	Other (Specify***)	P	P	P		P	P	P	Note 1,2,5,6
N=new indication; P=previously cleared by FDA(K122010); 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: Biopsy Guidance									
Note 3: iScape									
Note 4: TDI									
Note5: Color M									
Note6: Smart3D									
Note7: 4D(Real-time 3D)									
Note8: Strain Elastography									
Note 9: Contrast imaging (Contrast agent for Liver)									
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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)									

System: Z6 Diagnostic Ultrasound System

Transducer: 7L4P

Intended Use:

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

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

N=new indication; P=previously cleared by FDA(K122010); 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: Biopsy Guidance

Note 3: iScape

Note 4: TDI

Note5: Color M

Note6: Smart3D

Note7: 4D(Real-time 3D)

Note8: Strain Elastography

Note 9: Contrast imaging (Contrast agent for Liver)

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

System: Z6 Diagnostic Ultrasound System

Transducer: 7L5P

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

Clinical Application		Mode of Operation							
General (Track 1)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal	P	P	P		P	P	P	Note 1,2,3,6
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	P	Note 1,2,3,6
	Small Organ (Specify**)	P	P	P		P	P	P	Note 1,2,3,6
	Neonatal Cephalic	P	P	P		P	P	P	Note 1,2,3,6
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	P	P	P		P	P	P	Note 1,2,3,6
	Musculo-skeletal (Superficial)	P	P	P		P	P	P	Note 1,2,3,6
	Intravascular								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel	P	P	P		P	P	P	Note 1,2,3,6
	Other (Specify***)								
N=new indication; P=previously cleared by FDA(K122010); 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: Biopsy Guidance									
Note 3: iScape									
Note 4: TDI									
Note5: Color M									
Note6: Smart3D									
Note7: 4D(Real-time 3D)									
Note8: Strain Elastography									
Note 9: Contrast imaging (Contrast agent for Liver)									
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE NEEDED)									
Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)									

System: Z6 Diagnostic Ultrasound System

Transducer: L14-6P

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

Clinical Application		Mode of Operation							
General (Track 1)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal	P	P	P		P	P	P	Note 1,2,3,6
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	P	Note 1,2,3,6
	Small Organ (Specify**)	P	P	P		P	P	P	Note 1,2,3,6
	Neonatal Cephalic	P	P	P		P	P	P	Note 1,2,3,6
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	P	P	P		P	P	P	Note 1,2,3,6
	Musculo-skeletal (Superficial)	P	P	P		P	P	P	Note 1,2,3,6
	Intravascular								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel	P	P	P		P	P	P	Note 1,2,3,6
	Other (Specify***)								
N=new indication; P=previously cleared by FDA(K122010); 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: Biopsy Guidance									
Note 3: iScape									
Note 4: TDI									
Note5: Color M									
Note6: Smart3D									
Note7: 4D(Real-time 3D)									
Note8: Strain Elastography									
Note 9: Contrast imaging (Contrast agent for Liver)									
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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)									

System: Z6 Diagnostic Ultrasound System

Transducer: CB10-4P

intended Use:

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

Clinical Application		Mode of Operation							
General (Track 1)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify**)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal	P	P	P		P	P	P	Note 1,2,5,6
	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 1,2,5,6
N=new indication; P=previously cleared by FDA(K122010); 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.									
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Note 1: Tissue Harmonic Imaging.									
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Note5: Color M									
Note6: Smart3D									
Note7: 4D(Real-time 3D)									
Note8: Strain Elastography									
Note 9: Contrast imaging (Contrast agent for Liver)									
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE NEEDED)									
Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)									

System: Z6 Diagnostic Ultrasound System

Transducer: 2P2P

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

Clinical Application		Mode of Operation							
General (Track 1)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal	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								
	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(K122010); 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.									
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Note 3: iScape									
Note 4: TDI									
Note5: Color M									
Note6: Smart3D									
Note7: 4D(Real-time 3D)									
Note8: Strain Elastography									
Note 9: Contrast imaging (Contrast agent for Liver)									
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE NEEDED)									
Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)									

System: Z6 Diagnostic Ultrasound System

Transducer: V10-4BP

Intended Use:

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

Clinical Application		Mode of Operation							
General (Track 1)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	P	P	P		P	P	P	Note 1,2,5,6
	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 1,2,5,6
	Trans-vaginal	P	P	P		P	P	P	Note 1,2,5,6
	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 1,2,5,6
N=new indication; P=previously cleared by FDA(K122010); 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: Biopsy Guidance									
Note 3: iScape									
Note 4: TDI									
Note5: Color M									
Note6: Smart3D									
Note7: 4D(Real-time 3D)									
Note8: Strain Elastography									
Note 9: Contrast imaging (Contrast agent for Liver)									
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE NEEDED)									
Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)									

System: Z6 Diagnostic Ultrasound System

Transducer: 7LT4P

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

Clinical Application		Mode of Operation							
General (Track 1)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal	P	P	P		P	P	P	Note 1,2,3,6
	Intra-operative (Specify*)	P	P	P		P	P	P	Note 1,2,3,6
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	P	Note 1,2,3,6
	Small Organ (Specify**)	P	P	P		P	P	P	Note 1,2,3,6
	Neonatal Cephalic	P	P	P		P	P	P	Note 1,2,3,6
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	P	P	P		P	P	P	Note 1,2,3,6
	Musculo-skeletal (Superficial)	P	P	P		P	P	P	Note 1,2,3,6
Intravascular									
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel	P	P	P		P	P	P	Note 1,2,3,6
	Other (Specify***)								
N=new indication; P=previously cleared by FDA(K122010); 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: Biopsy Guidance									
Note 3: iScape									
Note 4: TDI									
Note5: Color M									
Note6: Smart3D									
Note7: 4D(Real-time 3D)									
Note8: Strain Elastography									
Note 9: Contrast imaging (Contrast agent for Liver)									
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE NEEDED)									
Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)									

System: Z6 Diagnostic Ultrasound System

Transducer: 6LE7P

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

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

N=new indication; P=previously cleared by FDA(K122010); 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: Biopsy Guidance

Note 3: iScape

Note 4: TDI

Note5: Color M

Note6: Smart3D

Note7: 4D(Real-time 3D)

Note8: Strain Elastography

Note 9: Contrast imaging (Contrast agent for Liver)

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

System: Z6 Diagnostic Ultrasound System

Transducer: P7-3P

intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track 1)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal	N	N	N	N	N	N	N	Note 1,2,4,5,6
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	N	N	N	N	N	N	N	Note 1,2,4,5,6
	Small Organ (Specify**)								
	Neonatal Cephalic	N	N	N	N	N	N	N	Note 1,2,4,5,6
	Adult Cephalic	N	N	N	N	N	N	N	Note 1,2,4,5,6
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	N	N	N	N	N	N	N	Note 1,2,4,5,6
	Musculo-skeletal (Superficial)								
Intravascular									
Cardiac	Cardiac Adult	N	N	N	N	N	N	N	Note 1,2,4,5,6
	Cardiac Pediatric	N	N	N	N	N	N	N	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(K172970); 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: Biopsy Guidance									
Note 3: iScape									
Note 4: TDI									
Note5: Color M									
Note6: Smart3D									
Note7: 4D(Real-time 3D)									
Note8: Strain Elastography									
Note 9: Contrast imaging (Contrast agent for Liver)									
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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)									

System: Z6 Diagnostic Ultrasound System

Transducer: 35C50P

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

Clinical Application		Mode of Operation							
General (Track 1)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	P	P	P		P	P	P	Note 1,2,5,6
	Abdominal	P	P	P		P	P	P	Note 1,2,5,6,9
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	P	Note 1,2,5,6
	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 1,2,5,6
	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 1,2,5,6
	Other (Specify***)								

N=new indication; P=previously cleared by FDA(K173369); 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: Biopsy Guidance

Note 3: iScape

Note 4: TDI

Note5: Color M

Note6: Smart3D

Note7: 4D(Real-time 3D)

Note8: Strain Elastography

Note 9: Contrast imaging (Contrast agent for Liver)

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

System: Z6 Diagnostic Ultrasound System

Transducer: 75L38P

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

Clinical Application		Mode of Operation							
General (Track 1)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal	P	P	P		P	P	P	Note 1,2,3,6
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	P	Note 1,2,3,6
	Small Organ (Specify**)	P	P	P		P	P	P	Note 1,2,3,6,8
	Neonatal Cephalic	P	P	P		P	P	P	Note 1,2,3,6
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	P	P	P		P	P	P	Note 1,2,3,6,8
	Musculo-skeletal (Superficial)	P	P	P		P	P	P	Note 1,2,3,6,8
Intravascular									
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel	P	P	P		P	P	P	Note 1,2,3,6
	Other (Specify***)								
N=new indication; P=previously cleared by FDA(K173369); 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: Biopsy Guidance									
Note 3: iScape									
Note 4: TDI									
Note5: Color M									
Note6: Smart3D									
Note7: 4D(Real-time 3D)									
Note8: Strain Elastography									
Note 9: Contrast imaging (Contrast agent for Liver)									
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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)									

System: Z6 Diagnostic Ultrasound System

Transducer: D6-2P

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

Clinical Application		Mode of Operation							
General (Track 1)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	P	P	P		P	P	P	Note 1,2,5,7
	Abdominal	P	P	P		P	P	P	Note 1,2,5,7
	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)								
Cardiac	Intravascular								
	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
Peripheral vessel	Intra-cardiac								
	Peripheral vessel								
	Other (Specify***)								

N=new indication; P=previously cleared by FDA(K173369); 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: Biopsy Guidance

Note 3: iScape

Note 4: TDI

Note5: Color M

Note6: Smart3D

Note7: 4D(Real-time 3D)

Note8: Strain Elastography

Note 9: Contrast imaging (Contrast agent for Liver)

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

510(K) SUMMARY

K182603

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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Nanshan, Shenzhen, 518057, P. R. China

Date Prepared: September 15, 2018

2. Device Name: Z6 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:

Z6 Diagnostic Ultrasound System is a general purpose, portable, 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, 4D,

Smart3D,TDI, Color M, Elastography, Biopsy Guidance, Contrast imaging (Contrast agent for Liver) 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 and convex array.

4. Intended Use:

The Z6 Diagnostic Ultrasound System is applicable for adults, pregnant women, pediatric patients and neonates. It is intended for use in fetal, abdominal, intraoperative(abdominal, thoracic, and vascular), pediatric, small organ(breast, thyroid, testes), neonatal and adult cephalic, trans-rectal, trans-vaginal, musculo-skeletal(conventional, superficial), adult and pediatric cardiac, peripheral vessel and urology exams.

5. Summary of Modifications

This submission device is a modification to Z6 Diagnostic Ultrasound System previously cleared in K122010.

- **New Added Transducers:**

P7-3P

75L38P

35C50P

D6-2P

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

NGB-001

NGB-002

- **Main Added Features:**

Contrast Imaging (Contrast agent for Liver)

TDI

4D

Smart 3D

Color M

ECG

Free Xros M
iNeedle
Medsight
iWorks
iLive
ExFov
Elastography to 75L38P and 7L4P Probe

6. Comparison with Predicate Devices:

Z6 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	Z6	K122010
2. Reference device	Mindray	DC-30	K173369
3. Reference device	Mindray	M7	K172970
4. Reference device	Mindray	DC-70	K163690

Z6 has the same technological characteristics, is comparable in key safety and effectiveness features, and has the same intended uses and basic operating modes as the predicate devices. All systems transmit ultrasonic energy into patients and 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.

- Subject device Z6 has the same intended uses as the predicated device Z6(K122010)

Subject Device Z6	Predicate device Z6(K122010)
The Z6 Diagnostic Ultrasound System is applicable for adults, pregnant women, pediatric patients and neonates. It is intended	The Z6 Diagnostic Ultrasound System is applicable for adults, pregnant women, pediatric patients and neonates. It is intended for use in

for use in fetal, abdominal, intraoperative(abdominal, thoracic, and vascular), pediatric, small organ(breast, thyroid, testes), neonatal and adult cephalic, trans-rectal, trans-vaginal, musculo-skeletal(conventional, superficial), adult and pediatric cardiac, peripheral vessel and urology exams.	fetal, abdominal, intraoperative(abdominal, thoracic, and vascular), pediatric, small organ(breast, thyroid, testes), neonatal and adult cephalic, trans-rectal, trans-vaginal, musculo-skeletal(conventional, superficial), adult and pediatric cardiac, peripheral vessel and urology exams.
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Compared to the predicated devices Z6(K122010):

- The acoustic power levels of Z6 are below the limits of FDA, which is the same as the predicated device Z6(K122010).
- Z6 is designed in compliance with the FDA recognized electrical and physical safety standard, which is the same as the predicated device Z6(K122010).
- Z6 has the same performance specification as the predicate device Z6(K122010) except adding ECG, 4D, Smart 3D, Contrast imaging (Contrast agent for Liver), Elastography, Free Xros X. New added features are substantial equivalent with the predicated device DC-30(K173369) .
- Z6 has the same performance specification as the predicate device Z6(K122010) except adding TDI, Color M. New added features are substantial equivalent with the predicated device M7(K172970)
- Z6 has the same function specification as the predicate device Z6(K122010) except adding iNeedle, Medsight. New added features are substantial equivalent with the predicated device M7(K172970).
- Z6 has the same function specification as the predicate device Z6(K122010) except adding iWoks, iLive. New added features are substantial equivalent with the predicated device DC-70(K163690).
- The patient contact material of the new added transducers are tested under ISO 10993-1.
- The patient contact materials of the new added needle-guided bracket are cleared along with NGB-001(K172970) and NGB-002(K172970).
- The transducers are same except for adding P7-3P, 75L38P, 35C50P, D6-2P. All of

the new added probes are substantial equivalent with the predicated device listed below:

Subject device	Predicated device
Z6	
P7-3P	P7-3s(M7)
75L38P	75L38P(DC-30)
35C50P	35C50P(DC-30)
D6-2P	D6-2P(DC-30)

7. Non-clinical Tests:

Z6 Diagnostic Ultrasound System has been evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness as well as thermal, electrical and mechanical safety, and has been designed to conform with applicable medical safety standards. This device has been tested and evaluated under the following standards:

- AAMI / ANSI ES60601-1:2005/(R)2012 And A1:2012: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2 Edition 3: 2007: Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests (Edition 3)
- IEC 60601-2-37 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
- IEC 60601-1-6 Edition 3.1 2013: medical electrical equipment - part 1-6: general requirements for basic safety and essential performance - collateral standard: usability.
- ISO 14971 Second edition 2007: Medical devices - Application of risk management to medical devices
- UD 2: Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment Revision 3
- ISO10993-1 Fourth edition 2009: 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, Z6 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 Z6 Diagnostic Ultrasound System is substantially equivalent with respect to safety and effectiveness to devices currently cleared for market.