



Food and Drug Administration
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Silver Spring, MD 20993-0002

Shenzhen Mindray Bio-Medical Electronics Co., Ltd
% Mr. Zhai Pei
Engineer of Technical Regulation Department
Mindray Building, Keji 12th Road South
Hi-tech Industrial Park, Nanshan
Shenzhen 518057, Guangdong
CHINA

September 21, 2017

Re: K171891
Trade/Device Name: ZS3 and z.one Ultrasound Systems
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX
Dated: August 15, 2017
Received: August 21, 2017

Dear Mr. Pei:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, “Misbranding by reference to premarket notification” (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH’s Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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

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

Sincerely yours,



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)

K171891

Device Name

ZS3 and z.one pro Ultrasound Systems

Indications for Use (Describe)

The ZS3 and z.one pro Ultrasound Systems are intended for use by a qualified physician for ultrasound evaluation of Ophthalmic; Fetal; Abdominal (renal, GYN/Pelvic); Intra-operative (abdominal, thoracic(cardiac), and vascular); Intra-operative (Neuro); Pediatric; Small organ (thyroid, breast, testes, etc); Neonatal cephalic; Adult Cephalic/Transcranial; Trans-rectal; Trans-vaginal; Trans-esoph.(non-Card); Musculoskeletal(Conventional); Musculoskeletal(Superficial); Cardiac Adult; Cardiac Pediatric; Trans-esoph. (Cardiac); Intra-cardiac; Peripheral vessel.

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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System:	ZS3, z.one pro Ultrasound System							
Transducer:	System union of all transducer types							
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 ₂	CWD	Color Doppler ³	Combined Modes ⁴	Other
Ophthalmic	Ophthalmic	P		P		P	P	
Fetal Imaging & Other	Fetal	P	P	P	P	P	P	P ⁵ , P ⁹
	Abdominal ⁶	P	P	P	P	P	P	P ⁵ , P ⁹ , N ¹¹ , N ¹²
	Intra-operative (Specify) ⁷	P	P	P		P	P	P ⁵
	Intra-operative (Neuro)	P	P	P		P	P	P ⁵
	Laparoscopic							
	Pediatric	P	P	P	P	P	P	P ⁵ , P ⁹
	Small Organ (Thyroid, Breast, Testes, etc.)	P	P	P		P	P	P ⁵ , P ⁸
	Neonatal Cephalic	P	P	P	P	P	P	P ⁵
	Adult Cephalic/Transcranial	P	P	P	P	P	P	P ⁵
	Trans-rectal	P	P	P		P	P	P ⁵ , P ⁹
	Trans-vaginal	P	P	P		P	P	P ⁵ , P ⁹
	Trans-urethral							
	Trans-esoph. (non-Card.)	P	P	P	P	P	P	P ⁵
	Musculo-skeletal (Conventional)	P	P	P		P	P	P ⁵ , P ⁸
	Musculo-skeletal (Superficial)	P	P	P		P	P	P ⁵ , P ⁸
	Intravascular							
Cardiac	Cardiac Adult	P ¹	P	P	P	P	P	P ⁵ , P ¹⁰
	Cardiac Pediatric	P	P	P	P	P	P	P ⁵ , N ¹⁰
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)	P	P	P	P	P	P	P ⁵ , N ¹⁰
	Intra-cardiac	P	P	P	P	P	P	N ¹⁰
	Other(Specify)							
Peripheral vessel	Peripheral vessel	P	P	P	P	P	P	P ⁵ , P ⁸ , P ⁹
	Other(Specify)							
N=new system indication; P=previously cleared by FDA;								
1 Includes B-Mode and Harmonic (Contrast) imaging (HI)								
2 Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)								
3 Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)								
4 Includes B+M, B+M+CM, M+CM, B+CD+M+CM, B+CD+PWD where CD could represent(CD, DPD, PD, or BD)								
5 Color M-Mode (CM)								
6 Abdominal includes renal, GYN/Pelvic								
7 Intra operative include (7.1 abdominal, 7.2 thoracic (Cardiac) and 7.3 vascular (PV))								
8 Freehand tissue elasticity								
9 3D/4D								
10 CEUS (Contrast agent for LVO)								
11 CEUS (Contrast agent for Liver)								
12 ARFI								

System:	ZS3, z.one pro Ultrasound System							
Transducer:	Curvilinear Transducer C4-1							
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 ₂	CWD	Color Doppler ³	Combined Modes ⁴	Other
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P	P	P	P	
	Abdominal ⁶	P	P	P	P	P	P	N ¹¹ , N ¹²
	Intra-operative (Specify) ⁷							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	P	P	P		P	P	
	Small Organ (Thyroid, Breast, Testes, etc.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)	P	P	P		P		
	Musculo-skeletal (Superficial)							
	Intravascular							
Cardiac	Cardiac Adult	P ¹	P	P	P	P	P	P ¹⁰
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other(Specify)							
Peripheral vessel	Peripheral vessel							
	Other(Specify)							
N=new system indication; P=previously cleared by FDA;								
1 Includes B-Mode and Harmonic (Contrast) imaging (HI)								
2 Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)								
3 Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)								
4 Includes B+M, B+M+CM, M+CM, B+CD+M+CM, B+CD+PWD where CD could represent(CD, DPD, PD, or BD)								
5 Color M-Mode (CM)								
6 Abdominal includes renal, GYN/Pelvic								
7 Intra operative include (7.1 abdominal, 7.2 thoracic (Cardiac) and 7.3 vascular (PV))								
8 Freehand tissue elasticity								
9 3D/4D								
10 CEUS (Contrast agent for LVO)								
11 CEUS (Contrast agent for Liver)								
12 ARFI								

System:	ZS3, z.one pro Ultrasound System							
Transducer:	Curvilinear Transducer C6-2							
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 ₂	CWD	Color Doppler ³	Combined Modes ⁴	Other
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P		P	P	P ⁵
	Abdominal ⁶	P	P	P		P	P	P ⁵ , N ¹¹
	Intra-operative (Specify) ⁷							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	P	P	P		P	P	P ⁵
	Small Organ (Thyroid, Breast, Testes, etc.)							
	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							
	Other(Specify)							
Peripheral vessel	Peripheral vessel	P	P	P		P	P	P ⁵
	Other (Specify)							
N=new system indication; P=previously cleared by FDA;								
1 Includes B-Mode and Harmonic (Contrast) imaging (HI)								
2 Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)								
3 Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)								
4 Includes B+M, B+M+CM, M+CM, B+CD+M+CM, B+CD+PWD where CD could represent(CD, DPD, PD, or BD)								
5 Color M-Mode (CM)								
6 Abdominal includes renal, GYN/Pelvic								
7 Intra operative include (7.1 abdominal, 7.2 thoracic (Cardiac) and 7.3 vascular (PV))								
8 Freehand tissue elasticity								
9 3D/4D								
10 CEUS (Contrast agent for LVO)								
11 CEUS (Contrast agent for Liver)								
12 ARFI								

System:	ZS3, z.one pro Ultrasound System							
Transducer:	Curvilinear Transducer C9-3							
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 ₂	CWD	Color Doppler ³	Combined Modes ⁴	Other
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P		P	P	P ⁵
	Abdominal ⁶	P	P	P		P	P	P ⁵ , N ¹¹
	Intra-operative (Specify) ^{7.1, 7.3}	P	P	P		P	P	P ⁵
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	P	P	P		P	P	P ⁵
	Small Organ (Thyroid, Breast, Testes, etc.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)	P	P	P		P	P	P ⁵
	Musculo-skeletal (Superficial)	P	P	P		P	P	P ⁵
	Intravascular							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other(Specify)							
Peripheral vessel	Peripheral vessel	P	P	P		P	P	P ⁵
	Other (Specify)							
N=new system indication; P=previously cleared by FDA;								
1 Includes B-Mode and Harmonic (Contrast) imaging (HI)								
2 Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)								
3 Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)								
4 Includes B+M, B+M+CM, M+CM, B+CD+M+CM, B+CD+PWD where CD could represent(CD, DPD, PD, or BD)								
5 Color M-Mode (CM)								
6 Abdominal includes renal, GYN/Pelvic								
7 Intra operative include (7.1 abdominal, 7.2 thoracic (Cardiac) and 7.3 vascular (PV))								
8 Freehand tissue elasticity								
9 3D/4D								
10 CEUS (Contrast agent for LVO)								
11 CEUS (Contrast agent for Liver)								
12 ARFI								

System:	ZS3, z.one pro Ultrasound System							
Transducer:	Convex Transducer C10-3							
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 ₂	CWD	Color Doppler ³	Combined Modes ⁴	Other
Ophthalmic	Ophthalmic	P		P		P	P	
Fetal Imaging & Other	Fetal	P	P	P	P	P	P	P ⁵
	Abdominal ⁶	P	P	P	P	P	P	P ⁵ , N ¹¹
	Intra-operative (Specify) ⁷	P	P	P		P	P	P ⁵
	Intra-operative (Neuro)	P	P	P		P	P	P ⁵
	Laparoscopic							
	Pediatric	P	P	P	P	P	P	P ⁵
	Small Organ (Thyroid, Breast, Testes, etc.)							
	Neonatal Cephalic	P	P	P	P	P	P	P ⁵
	Adult Cephalic/Transcranial	P	P	P	P	P	P	P 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 ⁵ , N ¹⁰
	Cardiac Pediatric	P	P	P	P	P	P	P ⁵ , N ¹⁰
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other(Specify)							
Peripheral vessel	Peripheral vessel	P	P	P	P	P	P	P ⁵
	Other(Specify)							
N=new system indication; P=previously cleared by FDA;								
1 Includes B-Mode and Harmonic (Contrast) imaging (HI)								
2 Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)								
3 Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)								
4 Includes B+M, B+M+CM, M+CM, B+CD+M+CM, B+CD+PWD where CD could represent(CD, DPD, PD, or BD)								
5 Color M-Mode (CM)								
6 Abdominal includes renal, GYN/Pelvic								
7 Intra operative include (7.1 abdominal, 7.2 thoracic (Cardiac) and 7.3 vascular (PV))								
8 Freehand tissue elasticity								
9 3D/4D								
10 CEUS (Contrast agent for LVO)								
11 CEUS (Contrast agent for Liver)								
12 ARFI								

System:	ZS3, z.one pro Ultrasound System							
Transducer:	Curvilinear Transducer C8-3 3D							
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 ₂	CWD	Color Doppler ³	Combined Modes ⁴	Other
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P		P	P	P ⁵ , P ⁹
	Abdominal ⁶	P	P	P		P	P	P ⁵ , P ⁹ , N ¹¹
	Intra-operative (Specify) ⁷							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	P	P	P		P	P	P ⁵ , P ⁹
	Small Organ (Thyroid, Breast, Testes, etc.)							
	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							
	Other(Specify)							
Peripheral vessel	Peripheral vessel	P	P	P		P	P	P ⁵ , P ⁹
	Other(Specify)							
N=new system indication; P=previously cleared by FDA;								
1 Includes B-Mode and Harmonic (Contrast) imaging (HI)								
2 Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)								
3 Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)								
4 Includes B+M, B+M+CM, M+CM, B+CD+M+CM, B+CD+PWD where CD could represent(CD, DPD, PD, or BD)								
5 Color M-Mode (CM)								
6 Abdominal includes renal, GYN/Pelvic								
7 Intra operative include (7.1 abdominal, 7.2 thoracic (Cardiac) and 7.3 vascular (PV))								
8 Freehand tissue elasticity								
9 3D/4D								
10 CEUS (Contrast agent for LVO)								
11 CEUS (Contrast agent for Liver)								
12 ARFI								

System:	ZS3, z.one pro Ultrasound System							
Transducer:	Phased (Sector) Array Transducer P4-1c							
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 ₂	CWD	Color Doppler ³	Combined Modes ⁴	Other
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P	P	P	P	P ⁵
	Abdominal ⁶	P	P	P	P	P	P	P ⁵ , N ¹¹
	Intra-operative (Specify) ⁷							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	P	P	P	P	P	P	P ⁵
	Small Organ (Thyroid, Breast, Testes, etc.)							
	Neonatal Cephalic	P	P	P	P	P	P	P ⁵
	Adult Cephalic/Transcranial	P	P	P	P	P	P	P ⁵
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
Cardiac	Cardiac Adult	P ¹	P	P	P	P	P	P ⁵ , P ¹⁰
	Cardiac Pediatric	P	P	P	P	P	P	P ⁵
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other(Specify)							
Peripheral vessel	Peripheral vessel	P	P	P	P	P	P	P ⁵
	Other (Specify)							
N=new system indication; P=previously cleared by FDA;								
1 Includes B-Mode and Harmonic (Contrast) imaging (HI)								
2 Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)								
3 Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)								
4 Includes B+M, B+M+CM, M+CM, B+CD+M+CM, B+CD+PWD where CD could represent(CD, DPD, PD, or BD)								
5 Color M-Mode (CM)								
6 Abdominal includes renal, GYN/Pelvic								
7 Intra operative include (7.1 abdominal, 7.2 thoracic (Cardiac) and 7.3 vascular (PV))								
8 Freehand tissue elasticity								
9 3D/4D								
10 CEUS (Contrast agent for LVO)								
11 CEUS (Contrast agent for Liver)								
12 ARFI								

System:	ZS3, z.one pro Ultrasound System							
Transducer:	Endo-Cavity Transducer E9-3							
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 ₂	CWD	Color Doppler ³	Combined Modes ⁴	Other
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P		P	P	P ⁵
	Abdominal ⁶							
	Intra-operative (Specify) ⁷							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Thyroid, Breast, Testes, etc.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	P	P	P		P	P	P ⁵
	Trans-vaginal	P	P	P		P	P	P ⁵
	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							
	Other(Specify)							
Peripheral vessel	Peripheral vessel							
	Other (Specify)							
N=new system indication; P=previously cleared by FDA;								
1 Includes B-Mode and Harmonic (Contrast) imaging (HI)								
2 Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)								
3 Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)								
4 Includes B+M, B+M+CM, M+CM, B+CD+M+CM, B+CD+PWD where CD could represent(CD, DPD, PD, or BD)								
5 Color M-Mode (CM)								
6 Abdominal includes renal, GYN/Pelvic								
7 Intra operative include (7.1 abdominal, 7.2 thoracic (Cardiac) and 7.3 vascular (PV))								
8 Freehand tissue elasticity								
9 3D/4D								
10 CEUS (Contrast agent for LVO)								
11 CEUS (Contrast agent for Liver)								
12 ARFI								

System:	ZS3, z.one pro Ultrasound System							
Transducer:	Endo-Cavity Transducer E9-4							
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 ₂	CWD	Color Doppler ³	Combined Modes ⁴	Other
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P		P	P	P ⁵
	Abdominal ⁶							
	Intra-operative (Specify) ⁷							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Thyroid, Breast, Testes, etc.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	P	P	P		P	P	P ⁵
	Trans-vaginal	P	P	P		P	P	P ⁵
	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							
	Other(Specify)							
Peripheral vessel	Peripheral vessel							
	Other (Specify)							
N=new system indication; P=previously cleared by FDA;								
1 Includes B-Mode and Harmonic (Contrast) imaging (HI)								
2 Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)								
3 Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)								
4 Includes B+M, B+M+CM, M+CM, B+CD+M+CM, B+CD+PWD where CD could represent(CD, DPD, PD, or BD)								
5 Color M-Mode (CM)								
6 Abdominal includes renal, GYN/Pelvic								
7 Intra operative include (7.1 abdominal, 7.2 thoracic (Cardiac) and 7.3 vascular (PV))								
8 Freehand tissue elasticity								
9 3D/4D								
10 CEUS (Contrast agent for LVO)								
11 CEUS (Contrast agent for Liver)								
12 ARFI								

System:	ZS3, z.one pro Ultrasound System							
Transducer:	Endo-Cavity Transducer E9-3 3D							
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 ₂	CWD	Color Doppler ³	Combined Modes ⁴	Other
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P		P	P	P ⁵ , P ⁹
	Abdominal ⁶							
	Intra-operative (Specify) ⁷							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Thyroid, Breast, Testes, etc.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	P	P	P		P	P	P ⁵ , P ⁹
	Trans-vaginal	P	P	P		P	P	P ⁵ , P ⁹
	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							
	Other(Specify)							
Peripheral vessel	Peripheral vessel							
	Other(Specify)							
N=new system indication; P=previously cleared by FDA;								
1 Includes B-Mode and Harmonic (Contrast) imaging (HI)								
2 Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)								
3 Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)								
4 Includes B+M, B+M+CM, M+CM, B+CD+M+CM, B+CD+PWD where CD could represent(CD, DPD, PD, or BD)								
5 Color M-Mode (CM)								
6 Abdominal includes renal, GYN/Pelvic								
7 Intra operative include (7.1 abdominal, 7.2 thoracic (Cardiac) and 7.3 vascular (PV))								
8 Freehand tissue elasticity								
9 3D/4D								
10 CEUS (Contrast agent for LVO)								
11 CEUS (Contrast agent for Liver)								
12 ARFI								

System:	ZS3, z.one pro Ultrasound System							
Transducer:	Linear Transducer L10-5							
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 ₂	CWD	Color Doppler ³	Combined Modes ⁴	Other
Ophthalmic	Ophthalmic	P		P		P	P	
Fetal Imaging & Other	Fetal	P	P	P		P	P	P ⁵
	Abdominal ⁶	P	P	P		P	P	P ⁵ , N ¹¹
	Intra-operative (Specify) ⁷	P	P	P		P	P	P ⁵
	Intra-operative (Neuro)	P		P		P	P	P ⁵
	Laparoscopic							
	Pediatric	P	P	P		P	P	P ⁵
	Small Organ (Thyroid, Breast, Testes, etc.)	P	P	P		P	P	P ⁵ , P ⁸
	Neonatal Cephalic	P	P	P		P	P	P ⁵
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)	P	P	P		P	P	P ⁵ , P ⁸
	Musculo-skeletal (Superficial)	P	P	P		P	P	P ⁵ , P ⁸
	Intravascular							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other(Specify)							
Peripheral vessel	Peripheral vessel	P	P	P		P	P	P ⁵ , P ⁸
	Other(Specify)							
N=new system indication; P=previously cleared by FDA;								
1 Includes B-Mode and Harmonic (Contrast) imaging (HI)								
2 Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)								
3 Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)								
4 Includes B+M, B+M+CM, M+CM, B+CD+M+CM, B+CD+PWD where CD could represent(CD, DPD, PD, or BD)								
5 Color M-Mode (CM)								
6 Abdominal includes renal, GYN/Pelvic								
7 Intra operative include (7.1 abdominal, 7.2 thoracic (Cardiac) and 7.3 vascular (PV))								
8 Freehand tissue elasticity								
9 3D/4D								
10 CEUS (Contrast agent for LVO)								
11 CEUS (Contrast agent for Liver)								
12 ARFI								

System:	ZS3, z.one pro Ultrasound System							
Transducer:	Linear Transducer L8-3							
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 ₂	CWD	Color Doppler ³	Combined Modes ⁴	Other
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P		P	P	P ⁵
	Abdominal ⁶	P	P	P		P	P	P ⁵ , N ¹¹
	Intra-operative (Specify) ⁷	P	P	P		P	P	P ⁵
	Intra-operative (Neuro)	P		P		P	P	P ⁵
	Laparoscopic							
	Pediatric	P	P	P		P	P	P ⁵
	Small Organ (Thyroid, Breast, Testes, etc.)	P	P	P		P	P	P ⁵ , P ⁸
	Neonatal Cephalic	P	P	P		P	P	P ⁵
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)	P	P	P		P	P	P ⁵ , P ⁸
	Musculo-skeletal (Superficial)	P	P	P		P	P	P ⁵ , P ⁸
	Intravascular							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other(Specify)							
Peripheral vessel	Peripheral vessel	P	P	P		P	P	P ⁵ , P ⁸
	Other(Specify)							
N=new system indication; P=previously cleared by FDA;								
1 Includes B-Mode and Harmonic (Contrast) imaging (HI)								
2 Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)								
3 Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)								
4 Includes B+M, B+M+CM, M+CM, B+CD+M+CM, B+CD+PWD where CD could represent(CD, DPD, PD, or BD)								
5 Color M-Mode (CM)								
6 Abdominal includes renal, GYN/Pelvic								
7 Intra operative include (7.1 abdominal, 7.2 thoracic (Cardiac) and 7.3 vascular (PV))								
8 Freehand tissue elasticity								
9 3D/4D								
10 CEUS (Contrast agent for LVO)								
11 CEUS (Contrast agent for Liver)								
12 ARFI								

System:	ZS3, z.one pro Ultrasound System							
Transducer:	Linear 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 ₂	CWD	Color Doppler ³	Combined Modes ⁴	Other
Ophthalmic	Ophthalmic	P		P		P	P	
Fetal Imaging & Other	Fetal	P	P	P		P	P	P ⁵
	Abdominal ⁶	P	P	P		P	P	P ⁵ , N ¹¹
	Intra-operative (Specify) ⁷	P	P	P		P	P	P ⁵
	Intra-operative (Neuro)	P		P		P	P	P ⁵
	Laparoscopic							
	Pediatric	P	P	P		P	P	P ⁵
	Small Organ (Thyroid, Breast, Testes, etc.)	P	P	P		P	P	P ⁵ , P ⁸
	Neonatal Cephalic	P	P	P		P	P	P ⁵
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)	P	P	P		P	P	P ⁵ , P ⁸
	Musculo-skeletal (Superficial)	P	P	P		P	P	P ⁵ , P ⁸
	Intravascular							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other(Specify)							
Peripheral vessel	Peripheral vessel	P	P	P		P	P	P ⁵ , P ⁸
	Other(Specify)							
N=new system indication; P=previously cleared by FDA;								
1 Includes B-Mode and Harmonic (Contrast) imaging (HI)								
2 Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)								
3 Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)								
4 Includes B+M, B+M+CM, M+CM, B+CD+M+CM, B+CD+PWD where CD could represent(CD, DPD, PD, or BD)								
5 Color M-Mode (CM)								
6 Abdominal includes renal, GYN/Pelvic								
7 Intra operative include (7.1 abdominal, 7.2 thoracic (Cardiac) and 7.3 vascular (PV))								
8 Freehand tissue elasticity								
9 3D/4D								
10 CEUS (Contrast agent for LVO)								
11 CEUS (Contrast agent for Liver)								
12 ARFI								

System:	ZS3, z.one pro Ultrasound System							
Transducer:	Linear Transducer L14-5w							
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 ₂	CWD	Color Doppler ³	Combined Modes ⁴	Other
Ophthalmic	Ophthalmic	P		P		P	P	
Fetal Imaging & Other	Fetal	P	P	P		P	P	P ⁵
	Abdominal ⁶	P	P	P		P	P	P ⁵ , N ¹¹
	Intra-operative (Specify) ⁷	P	P	P		P	P	P ⁵
	Intra-operative (Neuro)	P		P		P	P	P ⁵
	Laparoscopic							
	Pediatric	P	P	P		P	P	P ⁵
	Small Organ (Thyroid, Breast, Testes, etc.)	P	P	P		P	P	P ⁵ , P ⁸
	Neonatal Cephalic	P	P	P		P	P	P ⁵
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)	P	P	P		P	P	P ⁵ , P ⁸
	Musculo-skeletal (Superficial)	P	P	P		P	P	P ⁵ , P ⁸
	Intravascular							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other(Specify)							
Peripheral vessel	Peripheral vessel	P	P	P		P	P	P ⁵ , P ⁸
	Other(Specify)							
N=new system indication; P=previously cleared by FDA;								
1 Includes B-Mode and Harmonic (Contrast) imaging (HI)								
2 Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)								
3 Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)								
4 Includes B+M, B+M+CM, M+CM, B+CD+M+CM, B+CD+PWD where CD could represent(CD, DPD, PD, or BD)								
5 Color M-Mode (CM)								
6 Abdominal includes renal, GYN/Pelvic								
7 Intra operative include (7.1 abdominal, 7.2 thoracic (Cardiac) and 7.3 vascular (PV))								
8 Freehand tissue elasticity								
9 3D/4D								
10 CEUS (Contrast agent for LVO)								
11 CEUS (Contrast agent for Liver)								
12 ARFI								

System:	ZS3, z.one pro Ultrasound System							
Transducer:	Linear Transducer L20-5							
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 ₂	CWD	Color Doppler ³	Combined Modes ⁴	Other
Ophthalmic	Ophthalmic	P		P		P	P	
Fetal Imaging & Other	Fetal	P	P	P		P	P	P ⁵
	Abdominal ⁶	P	P	P		P	P	P ⁵ , N ¹¹
	Intra-operative (Specify) ⁷	P	P	P		P	P	P ⁵
	Intra-operative (Neuro)	P		P		P	P	P ⁵
	Laparoscopic							
	Pediatric	P	P	P		P	P	P ⁵
	Small Organ (Thyroid, Breast, Testes, etc.)	P	P	P		P	P	P ⁵ , P ⁸
	Neonatal Cephalic	P	P	P		P	P	P ⁵
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)	P	P	P		P	P	P ⁵ , P ⁸
	Musculo-skeletal (Superficial)	P	P	P		P	P	P ⁵ , P ⁸
	Intravascular							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other(Specify)							
Peripheral vessel	Peripheral vessel	P	P	P		P	P	P ⁵ , P ⁸
	Other(Specify)							
N=new system indication; P=previously cleared by FDA;								
1 Includes B-Mode and Harmonic (Contrast) imaging (HI)								
2 Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)								
3 Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)								
4 Includes B+M, B+M+CM, M+CM, B+CD+M+CM, B+CD+PWD where CD could represent(CD, DPD, PD, or BD)								
5 Color M-Mode (CM)								
6 Abdominal includes renal, GYN/Pelvic								
7 Intra operative include (7.1 abdominal, 7.2 thoracic (Cardiac) and 7.3 vascular (PV))								
8 Freehand tissue elasticity								
9 3D/4D								
10 CEUS (Contrast agent for LVO)								
11 CEUS (Contrast agent for Liver)								
12 ARFI								

System:									ZS3, z.one pro Ultrasound System								
Transducer:									Tran-Esophageal Transducer P8-3TEE								
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 ₂	CWD	Color Doppler ³	Combined Modes ⁴	Other		
Ophthalmic		Ophthalmic															
Fetal Imaging & Other		Fetal															
		Abdominal ⁶															
		Intra-operative (Specify) ⁷															
		Intra-operative (Neuro)															
		Laparoscopic															
		Pediatric															
		Small Organ (Thyroid, Breast, Testes, etc.)															
		Neonatal Cephalic															
		Adult Cephalic															
		Trans-rectal															
		Trans-vaginal															
		Trans-urethral															
		Trans-esoph. (non-Card.)							P	P	P	P	P	P	P ⁵		
		Musculo-skeletal (Conventional)															
		Musculo-skeletal (Superficial)															
		Intravascular															
Cardiac		Cardiac Adult															
		Cardiac Pediatric															
		Intravascular (Cardiac)															
		Trans-esoph. (Cardiac)							P	P	P	P	P	P	P ⁵ , N ¹⁰		
		Intra-cardiac															
		Other(Specify)															
Peripheral vessel		Peripheral vessel															
		Other(Specify)															
N=new system indication; P=previously cleared by FDA;																	
1 Includes B-Mode and Harmonic (Contrast) imaging (HI)																	
2 Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)																	
3 Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)																	
4 Includes B+M, B+M+CM, M+CM, B+CD+M+CM, B+CD+PWD where CD could represent(CD, DPD, PD, or BD)																	
5 Color M-Mode (CM)																	
6 Abdominal includes renal, GYN/Pelvic																	
7 Intra operative include (7.1 abdominal, 7.2 thoracic (Cardiac) and 7.3 vascular (PV))																	
8 Freehand tissue elasticity																	
9 3D/4D																	
10 CEUS (Contrast agent for LVO)																	
11 CEUS (Contrast agent for Liver)																	
12 ARFI																	

System:	ZS3, z.one pro Ultrasound System							
Transducer:	Phased (Sector) Array Transducer P9-3ic (St.Jude EP ViewFlex PLUS ICE Catheter model # VF-PM Part #09-2005 (off the shelf)							
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 ₂	CWD	Color Doppler ³	Combined Modes ⁴	Other
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal ⁶							
	Intra-operative (Specify) ⁷							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Thyroid, Breast, Testes, etc.)							
	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)								
Intra-cardiac		P	P	P	P	P	P	N ¹⁰
Peripheral vessel	Other (Specify)							
	Peripheral vessel							
N=new system indication; P=previously cleared by FDA;								
1 Includes B-Mode and Harmonic (Contrast) imaging (HI)								
2 Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)								
3 Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)								
4 Includes B+M, B+M+CM, M+CM, B+CD+M+CM, B+CD+PWD where CD could represent(CD, DPD, PD, or BD)								
5 Color M-Mode (CM)								
6 Abdominal includes renal, GYN/Pelvic								
7 Intra operative include (7.1 abdominal, 7.2 thoracic (Cardiac) and 7.3 vascular (PV))								
8 Freehand tissue elasticity								
9 3D/4D								
10 CEUS (Contrast agent for LVO)								
11 CEUS (Contrast agent for Liver)								
12 ARFI								

System:	ZS3, z.one pro Ultrasound System							
Transducer:	A2CW (Common name Pencil Probe)							
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 ₂	CWD	Color Doppler ³	Combined Modes ⁴	Other
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal ⁶							
	Intra-operative (Specify) ⁷							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric				P			
	Small Organ (Thyroid, Breast, Testes, etc.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Cardiac	Cardiac Adult				P		
Cardiac Pediatric					P			
Intravascular (Cardiac)								
Trans-esoph. (Cardiac)								
Intra-cardiac								
Other(Specify)								
Peripheral vessel	Peripheral vessel							
	Other (Specify)							
N=new system indication; P=previously cleared by FDA;								
1 Includes B-Mode and Harmonic (Contrast) imaging (HI)								
2 Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)								
3 Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)								
4 Includes B+M, B+M+CM, M+CM, B+CD+M+CM, B+CD+PWD where CD could represent(CD, DPD, PD, or BD)								
5 Color M-Mode (CM)								
6 Abdominal includes renal, GYN/Pelvic								
7 Intra operative include (7.1 abdominal, 7.2 thoracic (Cardiac) and 7.3 vascular (PV))								
8 Freehand tissue elasticity								
9 3D/4D								
10 CEUS (Contrast agent for LVO)								
11 CEUS (Contrast agent for Liver)								
12 ARFI								

System:	ZS3, z.one pro Ultrasound System							
Transducer:	A5CW (Common name Pencil Probe)							
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 ₂	CWD	Color Doppler ³	Combined Modes ⁴	Other
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal ⁶							
	Intra-operative (Specify) ⁷							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric				P			
	Small Organ (Thyroid, Breast, Testes, etc.)							
	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								
Other(Specify)								
Peripheral vessel	Peripheral vessel				P			
	Other(Specify)							
N=new system indication; P=previously cleared by FDA;								
1 Includes B-Mode and Harmonic (Contrast) imaging (HI)								
2 Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)								
3 Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)								
4 Includes B+M, B+M+CM, M+CM, B+CD+M+CM, B+CD+PWD where CD could represent(CD, DPD, PD, or BD)								
5 Color M-Mode (CM)								
6 Abdominal includes renal, GYN/Pelvic								
7 Intra operative include (7.1 abdominal, 7.2 thoracic (Cardiac) and 7.3 vascular (PV))								
8 Freehand tissue elasticity								
9 3D/4D								
10 CEUS (Contrast agent for LVO)								
11 CEUS (Contrast agent for Liver)								
12 ARFI								

System:	ZS3, z.one pro Ultrasound System							
Transducer:	Curvilinear Transducer C9-3sp							
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 ₂	CWD	Color Doppler ³	Combined Modes ⁴	Other
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P		P	P	P ⁵
	Abdominal ⁶	P	P	P		P	P	P ⁵ , N ¹¹
	Intra-operative (Specify) ^{7.1, 7.3}	P	P	P		P	P	P ⁵
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	P	P	P		P	P	P ⁵
	Small Organ (Thyroid, Breast, Testes, etc.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)	P	P	P		P	P	P ⁵
	Musculo-skeletal (Superficial)	P	P	P		P	P	P ⁵
	Intravascular							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other(Specify)							
Peripheral vessel	Peripheral vessel	P	P	P		P	P	P ⁵
	Other (Specify)							
N=new system indication; P=previously cleared by FDA;								
1 Includes B-Mode and Harmonic (Contrast) imaging (HI)								
2 Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)								
3 Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)								
4 Includes B+M, B+M+CM, M+CM, B+CD+M+CM, B+CD+PWD where CD could represent(CD, DPD, PD, or BD)								
5 Color M-Mode (CM)								
6 Abdominal includes renal, GYN/Pelvic								
7 Intra operative include (7.1 abdominal, 7.2 thoracic (Cardiac) and 7.3 vascular (PV))								
8 Freehand tissue elasticity								
9 3D/4D								
10 CEUS (Contrast agent for LVO)								
11 CEUS (Contrast agent for Liver)								
12 ARFI								

System:	ZS3, z.one pro Ultrasound System							
Transducer:	Curvilinear Transducer C6-1							
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 ₂	CWD	Color Doppler ³	Combined Modes ⁴	Other
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	N	N	N		N	N	N ⁵
	Abdominal ⁶	N	N	N		N	N	N ⁵ , N ¹¹
	Intra-operative (Specify) ⁷							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	N	N	N		N	N	N ⁵
	Small Organ (Thyroid, Breast, Testes, etc.)							
	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							
	Other(Specify)							
Peripheral vessel	Peripheral vessel	N	N	N		N	N	N ⁵
	Other (Specify)							
N=new system indication; P=previously cleared by FDA;								
1 Includes B-Mode and Harmonic (Contrast) imaging (HI)								
2 Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)								
3 Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)								
4 Includes B+M, B+M+CM, M+CM, B+CD+M+CM, B+CD+PWD where CD could represent(CD, DPD, PD, or BD)								
5 Color M-Mode (CM)								
6 Abdominal includes renal, GYN/Pelvic								
7 Intra operative include (7.1 abdominal, 7.2 thoracic (Cardiac) and 7.3 vascular (PV))								
8 Freehand tissue elasticity								
9 3D/4D								
10 CEUS (Contrast agent for LVO)								
11 CEUS (Contrast agent for Liver)								
12 ARFI								

System:	ZS3, z.one pro Ultrasound System							
Transducer:	Curvilinear Transducer C18-5							
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 ₂	CWD	Color Doppler ³	Combined Modes ⁴	Other
Ophthalmic	Ophthalmic	N		N		N	N	
Fetal Imaging & Other	Fetal	N	N	N		N	N	N ⁵
	Abdominal ⁶	N	N	N		N	N	N ⁵ , N ¹¹
	Intra-operative (Specify) ^{7.1, 7.3}							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Thyroid, Breast, Testes, etc.)	N	N	N		N	N	N ⁵
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)	N	N	N		N	N	N ⁵
	Musculo-skeletal (Superficial)	N	N	N		N	N	N ⁵
	Intravascular							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral vessel	Peripheral vessel	N	N	N		N	N	N ⁵
	Other (Specify)							
N=new system indication; P=previously cleared by FDA;								
1 Includes B-Mode and Harmonic (Contrast) imaging (HI)								
2 Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)								
3 Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)								
4 Includes B+M, B+M+CM, M+CM, B+CD+M+CM, B+CD+PWD where CD could represent(CD, DPD, PD, or BD)								
5 Color M-Mode (CM)								
6 Abdominal includes renal, GYN/Pelvic								
7 Intra operative include (7.1 abdominal, 7.2 thoracic (Cardiac) and 7.3 vascular (PV))								
8 Freehand tissue elasticity								
9 3D/4D								
10 CEUS (Contrast agent for LVO)								
11 CEUS (Contrast agent for Liver)								
12 ARFI								

System:	ZS3, z.one pro Ultrasound System							
Transducer:	Tran-Esophageal Transducer P8-3mTEE							
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 ₂	CWD	Color Doppler ³	Combined Modes ⁴	Other
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal ⁶							
	Intra-operative (Specify) ⁷							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Thyroid, Breast, Testes, etc.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)	N	N	N	N	N	N	N ⁵
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)	N	N	N	N	N	N	N ⁵ , N ¹⁰
	Intra-cardiac							
	Other (Specify)							
Peripheral vessel	Peripheral vessel							
	Other (Specify)							
N=new system indication; P=previously cleared by FDA;								
1 Includes B-Mode and Harmonic (Contrast) imaging (HI)								
2 Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)								
3 Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)								
4 Includes B+M, B+M+CM, M+CM, B+CD+M+CM, B+CD+PWD where CD could represent(CD, DPD, PD, or BD)								
5 Color M-Mode (CM)								
6 Abdominal includes renal, GYN/Pelvic								
7 Intra operative include (7.1 abdominal, 7.2 thoracic (Cardiac) and 7.3 vascular (PV))								
8 Freehand tissue elasticity								
9 3D/4D								
10 CEUS (Contrast agent for LVO)								
11 CEUS (Contrast agent for Liver)								
12 ARFI								

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.

1. Submitter:

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Date Prepared: June 12, 2017

2. Device Name: ZS3 and z.one pro Ultrasound Systems

Classification

Regulatory Class: II

Review Category: Tier II

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

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

21 CFR 892.1570 Diagnostic Ultrasound Transducer (90-ITX)

3. Device Description:

The ZS3 and z.one pro Ultrasound Systems are full-featured, general purpose, software controlled, diagnostic ultrasound systems used to acquire and display high-resolution, real-time ultrasound data through multiple imaging modes. The system utilizes zone technology which allows the system to collect more data at one time, thereby optimizing image quality.

The exam dependent default settings for the ZS3 and z.one pro allow the user to have minimum adjustment for imaging the patient, while the in depth soft-menu control

enables the advanced user to set the system based on image appearance preference. The architecture of the ZS3 and z.one pro Ultrasound Systems support system integration to a variety of upgradable options and features. Up to three transducers can be connected to the multi-transducer port permitting easy transducer transition. The system can be operated on either battery or AC power.

4. Intended Use:

The ZS3 and z.one pro Ultrasound Systems are intended for use by a qualified physician for ultrasound evaluation of Ophthalmic; Fetal; Abdominal (renal, GYN/Pelvic); Intra-operative (abdominal, thoracic(cardiac), and vascular); Intraoperative(Neuro); Pediatric; Small organ (thyroid, breast, testes, etc); Neonatal cephalic; Adult Cephalic/Transcranial; Trans-rectal; Trans-vaginal; Trans-esoph.(non-Card); Musculoskeletal(Conventional); Musculoskeletal(Superficial); Cardiac Adult; Cardiac Pediatric; Trans-esoph. (Cardiac); Intra-cardiac; Peripheral vessel.

5. Summary of Modifications and New Added Features

This submission is modification to ZS3 and z.one pro Ultrasound Systems previously cleared in K151175.

The following is a brief overview of the modifications and new added features.

- **Newly added transducers**

- C6-1, C18-5, P8-3mTEE

- **Newly added features**

- ARFI

- CEUS (Contrast agent for Liver)

- Add CEUS (Contrast agent for LVO) function to transducers C10-3, P8-3TEE, P9-3ic and P8-3mTEE

- Smart OB

- Smart NT

- Auto EF

- Auto IMT

- Stress Echo

- Anatomical M

- Needle-Guided bracket NGB-022(cleared in K141010)

6. Comparison to Predicate Devices:

The modified ZS3 and z.one pro Ultrasound Systems are comparable with and substantially equivalent to these predicate devices:

Predicate Device	Manufacturer	Model	510(k) Number
1	Zonare	ZS3, z.one pro	K151175
2	Mindray	DC-8	K170277
3	GE Healthcare	Voluson S8	K160184
4	GE Healthcare	Logiq E9	K163077
5	Mindray	M9	K152543

The modified ZS3 and z.one pro Ultrasound Systems employ 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 has the same intended use as the predicated device ZS3/z.one pro(K151175)

Items	Subject Device ZS3/z.one pro	Predicate device ZS3/z.one pro(K151175)
Intended Use	The ZS3 and z.one pro Ultrasound Systems are intended for use by a qualified physician for ultrasound evaluation of Opthalmic; Fetal; Abdominal (renal, GYN/Pelvic); Intra-operative (abdominal, thoracic(cardiac), and vascular); Intra-operative (Neuro); Pediatric; Small organ (thyroid, breast, testes, etc); Neonatal cephalic; Adult Cephalic/Transcranial; Trans-rectal; Trans-vaginal; Trans-esoph.(non-Card); Musculoskeletal(Conventional); Musculoskeletal(Superficial);	The ZS3 and z.one pro Ultrasound Systems are intended for use by a qualified physician for ultrasound evaluation of Ophthalmic; Fetal/obstetric, gynecological; Abdominal(renal, GYN/Pelvic); Intra-operative (abdominal, thoracic, and vascular), Intra-operative neurological; Pediatric: small organ (thyroid, breast, testes, etc), Adult & Neonatal Cephalic; Trans-rectal,

	Cardiac Adult; Cardiac Pediatric; Trans-esoph. (Cardiac); Intra-cardiac; Peripheral vessel.	Trans-vaginal, Trans-cranial, Trans-esophageal (non-cardiac and cardiac); Musculoskeletal (conventional & superficial); 3D/4D; Cardiac - Adult/ Pediatric/ Fetal; Echo, Intra-Cardiac; Pelvic; Peripheral vascular; harmonic tissue and contrast imaging and Tissue elasticity.
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- The patient contact materials of the new added transducers and needle-guided bracket are tested under ISO 10993-1.
- The acoustic power levels of modified ZS3 and z.one pro are below the limits of FDA, which are the same as the predicated device ZS3 and z.one pro (K151175).
- The modified ZS3 and z.one pro are designed in compliance with the FDA recognized electrical and physical safety standards, which are the same as the predicated device ZS3 and z.one pro (K151175).
- The modified ZS3 and z.one pro have the same imaging modes as the predicated devices.
- The new added features of modified ZS3 and z.one pro are the same as the predicated devices.
- The modified ZS3 and z.one pro have similar transducers with the predicated devices.

7. Non-clinical Tests:

ZS3 and z.one pro Ultrasound Systems have been evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness as well as thermal, electrical and mechanical safety, and has been found to conform with applicable medical safety standards. Non-clinical tests relied on in this premarket notification submission for a determination of substantial equivalence include testing showing compliance with the following standards:

- AAMI/ANSI ES60601-1: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

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

8. Clinical Tests:

Not Applicable.

Conclusion:

Intended uses and other key features are consistent with traditional clinical practices, FDA guidelines and established methods of patient examination. The design, development and quality process of the manufacturer confirms with 21 CFR 820, ISO 9001 and ISO 13485 quality systems. The device conforms to applicable medical device safety standards. Therefore, the ZS3 and z.one pro Ultrasound Systems are substantially equivalent with respect to safety and effectiveness to devices currently cleared for market.