



December 19, 2019

ShenZhen Mindray Bio-Medical Electronics Co., Ltd.
% Jiang Haosen
Engineer of Technical Regulation
Keji 12th Road South, High-tech Industrial Park,
Shenzhen, Guangdong 518057
CHINA

Re: K192410

Trade/Device Name: ZS3 and z.one pro Ultrasound Systems
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: November 15, 2019
Received: November 18, 2019

Dear Jiang Haosen:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); 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 <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). 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 (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K192410

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); Laparoscopic; 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 , P ¹¹ , P ¹² , N ¹³
	Intra-operative (Specify) ⁷	P	P	P		P	P	P ⁵
	Intra-operative (Neuro)	P	P	P		P	P	P ⁵
	Laparoscopic	N	N	N		N	N	N ⁵ , N ¹¹
	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 , P ¹⁰
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)	P	P	P	P	P	P	P ⁵ , P ¹⁰
	Intra-cardiac	P	P	P	P	P	P	P ¹⁰ , N ⁵
	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								
13 2D SWI								

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	N ⁵
	Abdominal ⁶	P	P	P	P	P	P	P ¹¹ , P ¹² , N ⁵ , N ¹³
	Intra-operative (Specify) ⁷							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	P	P	P		P	P	N ⁵
	Small Organ (Thyroid, Breast, Testes, etc.)							
	Neonatal Cephalic							
	Adult Cephalic/Transcranial							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)	P	P	P		P		N ⁵
	Musculo-skeletal (Superficial)							
	Intravascular							
Cardiac	Cardiac Adult	P ¹	P	P	P	P	P	P ¹⁰ , N ⁵
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other(Specify)							
Peripheral vessel	Peripheral vessel	N	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								
13 2D SWI								

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 , P 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/Transcranial							
	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								
13 2D SWI								

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 , P 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.)	N	N	N		N	N	N ⁵
	Neonatal Cephalic							
	Adult Cephalic/Transcranial							
	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								
13 2D SWI								

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 , p 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 , p ¹⁰
	Cardiac Pediatric	P	P	P	P	P	P	p ⁵ , p 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								
13 2D SWI								

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 , P 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/Transcranial							
	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								
13 2D SWI								

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 , p 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								
13 2D SWI								

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	N	N	N		N	N	N ⁵
	Intra-operative (Specify) ⁷							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Thyroid, Breast, Testes, etc.)							
	Neonatal Cephalic							
	Adult Cephalic/Transcranial							
	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								
13 2D SWI								

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	N	N	N		N	N	N ⁵
	Intra-operative (Specify) ⁷							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Thyroid, Breast, Testes, etc.)							
	Neonatal Cephalic							
	Adult Cephalic/Transcranial							
	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								
13 2D SWI								

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	N	N	N		N	N	N ⁵ , N ⁹
	Intra-operative (Specify) ⁷							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Thyroid, Breast, Testes, etc.)							
	Neonatal Cephalic							
	Adult Cephalic/Transcranial							
	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								
13 2D SWI								

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 , p 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/Transcranial							
	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								
13 2D SWI								

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 , p 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/Transcranial							
	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								
13 2D SWI								

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 , p 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/Transcranial							
	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								
13 2D SWI								

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 , p 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/Transcranial							
	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								
13 2D SWI								

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 , p 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/Transcranial							
	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								
13 2D SWI								

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/Transcranial							
	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 , P 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								
13 2D SWI								

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/Transcranial							
	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	P	P	P	P	P	P	P ¹⁰ , N ⁵
	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								
13 2D SWI								

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/Transcranial							
	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								
13 2D SWI								

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/Transcranial							
	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								
13 2D SWI								

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 , P 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/Transcranial							
	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								
13 2D SWI								

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	P	P	P		P	P	P ⁵
	Abdominal ⁶	P	P	P		P	P	P ⁵ , P 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/Transcranial							
	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								
13 2D SWI								

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	P		P		P	P	
Fetal Imaging & Other	Fetal	P	P	P		P	P	P ⁵
	Abdominal ⁶	P	P	P		P	P	P ⁵ , P ¹¹
	Intra-operative (Specify) ⁷	N	N	N		N	N	N ⁵
	Intra-operative (Neuro)	N	N	N		N	N	N ⁵
	Laparoscopic							
	Pediatric	N	N	N		N	N	N ⁵
	Small Organ (Thyroid, Breast, Testes, etc.)	P	P	P		P	P	P ⁵
	Neonatal Cephalic	N	N	N		N	N	N ⁵
	Adult Cephalic/Transcranial							
	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								
13 2D SWI								

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/Transcranial							
	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 , P 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								
13 2D SWI								

System:	ZS3, z.one pro Ultrasound System							
Transducer:	L30-8							
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							
	Abdominal ⁶							
	Intra-operative (Specify) ⁷							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Thyroid, Breast, Testes, etc.)	N	N	N		N	N	N ⁵
	Neonatal Cephalic	N	N	N		N	N	N ⁵
	Adult Cephalic/Transcranial							
	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								
13 2D SWI								

System:	ZS3, z.one pro Ultrasound System							
Transducer:	P7-3c							
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	N ⁵
	Abdominal ⁶	N	N	N	N	N	N	N ⁵ , N ¹¹
	Intra-operative (Specify) ⁷							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	N	N	N	N	N	N	N ⁵
	Small Organ (Thyroid, Breast, Testes, etc.)							
	Neonatal Cephalic	N	N	N	N	N	N	N ⁵
	Adult Cephalic/Transcranial	N	N	N	N	N	N	N ⁵
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
Cardiac	Cardiac Adult	N	N	N	N	N	N	N ⁵ , N ¹⁰
	Cardiac Pediatric	N	N	N	N	N	N	N ⁵
	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								
13 2D SWI								

System:	ZS3, z.one pro Ultrasound System							
Transducer:	C12-4lp							
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	N	N	N		N	N	N ⁵ , N ¹¹
	Pediatric							
	Small Organ (Thyroid, Breast, Testes, etc.)							
	Neonatal Cephalic							
	Adult Cephalic/Transcranial							
	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							
	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								
13 2D SWI								

510(K) SUMMARY

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

1. Submitter:

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Date Prepared: August 30, 2019

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. Indications for 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); Laparoscopic; 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 K171891.

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

- **Newly added transducers**
L30-8, P7-3c, C12-4lp
- **Newly added features**
2D SWI
CEUS QI
Needle OPT
TTQA
HD Scope
Add CM (Color M-Mode) function to transducers C4-1, P9-3ic
Protocol
MV slope measurement
- **Newly added Exam Mode**
Vascular for C4-1; Small Parts for C9-3; Abdominal for E9-3, E9-4 and E9-3 3D;
Intra-operative, Pediatric and NeoHead for C18-5
- **Material changed for some previous licensed transducers**
Mucilage glue is changed from RTV 167 to RTV 162 for transducer C4-1, C6-2, P4-1c, C9-3, C10-3, L8-3, L14-5w, L10-5, L14-5sp.
- **Newly added accessories**
Gel Warmer; wireless Ethernet Routers and Bridges

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. Primary predicate device	Mindray	ZS3, z.one pro	K171891
2. Reference device	Hitachi	Noblus™	K160559
3. Reference device	Mindray	Resona 7	K171233
4. Reference device	GE Healthcare	Logiq P9	K181783

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 indications for use and basic operating modes as the predicate devices.

- Subject device has the same indications for use as the predicated device ZS3/z.one pro(K171891); laparoscopic as the predicated device NOBLUS™ (K160559)
- The patient contact materials of the new added transducers, material changed transducers and newly added intra-operative application for previous licensed transducers 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 (K171891).
- 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 (K171891).
- 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 ES60601-1:2005/(R)2012 and A1:2012, c1:2009/(r)2012 and a2:2010/(r)2012 (consolidated text) medical electrical equipment - part 1: general requirements for basic safety and essential performance (iec 60601-1:2005, mod).
- IEC 60601-1-2 Edition 4.0 2014-02
Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC 60601-2-37 Edition 2.1 2015
Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
- IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION
Medical device software - Software life cycle processes
- ISO 14971 Second edition 2007-03-01
Medical devices - Application of risk management to medical devices
- NEMA UD 2-2004 (R2009), acoustic output measurement standard for diagnostic ultrasound equipment revision 3.
- AAMI / ANSI / ISO 10993-1:2009/(R)2013, biological evaluation of medical devices - part 1: evaluation and testing within a risk management process.

8. Clinical Tests:

Not Applicable. The subject of this submission, ZS3 and z.one pro Ultrasound Systems, do not require clinical studies to support substantial equivalence.

Conclusion:

Indications for Use 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.