K141641

JUL 18 2014

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ZONARE

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

General Information

Applicant:	ZONARE Medical Systems, Inc. 420 N. Bernardo Avenue Mountain View, CA 94043		
Contact Person:	Dan Bradford Vice President, Operations Phone: (650) 316-3113 Facsimile: (650) 967-9056 E-mail: dbradford@zonare.com		
Date Prepared:	April 24, 2014		
Trade Name(s):	ZS3 Ultrasound System z.one$_{pro}$ Ultrasound System		
Common Name:	Diagnostic Ultrasound System with Accessories		
Classification:	II		
Classification Name(s):	Ultrasonic Pulsed Doppler Imaging System	Ultrasonic Pulsed Echo Imaging System	Diagnostic Ultrasound Transducer
Regulation Number:	21 CFR 892.1550	892.1560	892.1570
Product Code:	IYN	IYO	ITX
Classification Panel:	Radiology		
Predicate Devices:	ZONARE's ZS3 Ultrasound System		K120703
	ZONARE's z.one ultra Ultrasound System		K101091

Device Description

The ZS3 and z.one$_{pro}$ Ultrasound Systems (hereafter referred to as "ZS3 Ultrasound Platform" or "ZS3" for simplicity) 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 platform utilizes ZONARE's patented 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 allows 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

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based on image appearance preference. The architecture of the ZS3 Ultrasound Platform supports system integration to a variety of upgradable options and features. Up to three ZONARE transducers can be connected to the multi-transducer port permitting easy transducer transition. The ZS3 Ultrasound Platform can be operated on either battery or AC power.

Intended Use

The device is 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, Trans-vaginal, Trans-cranial, Trans-esophageal (non-cardiac and cardiac); Musculosketal (conventional & superficial); 3D/4D; Cardiac - Adult/ Pediatric/ Fetal; Echo, Intra-Cardiac; Pelvic; Peripheral vascular; harmonic tissue and contrast imaging and Tissue elasticity.

Comparison of ZONARE ZS3 Ultrasound Platform to the Predicate Devices

Item	ZS3 Ultrasound Platform ZS3 and z.one$_{pro}$ Ultrasound Systems (ZONARE Medical Systems)	ZS3 (ZONARE Medical Systems)	z.one ultra and z.one ultra SP (ZONARE Medical Systems)
510(k) Number	Current Submission	K120703	K101091
Intended Use	Diagnostic ultrasound imaging or fluid flow analysis of the human body.	Same	Same
Indications for Use	The z.one$_{pro}$ is 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, 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.	Same	Same
Design	Diagnostic zone technology ultrasound based platform	Same	Same
Safety Standards	IEC 60601-1 IEC 60601-2-37 IEC 60601-1-2 ISO 10993-1, -5, 10, -12 AIUM, NEMA UD 2, NEMA UD3	Same	Same
Patient Contact Materials	Complies with ISO 10993	Same	Same
Mode of Operations	B-Mode, M-Mode, PWD Mode, CWD, CD Mode, Elastorgraphy, Contrast Enhanced, 3D/4D, ECG (for cardiac cycle referenced timing only) Combined Modes include B+CD, B+PW,	Same	Same

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Item	ZS3 Ultrasound Platform ZS3 and z.one $_{pro}$ Ultrasound Systems (ZONARE Medical Systems)	ZS3 (ZONARE Medical Systems)	z.one ultra and z.one ultra SP (ZONARE Medical Systems)
	B+CD+PW, B+M, M+CM, B+CD+M+CM, B+Elastorgraphy, B+CEUS, and + ECG Trace		
Measurements	B-Mode (2D): Depth, Distance, Circ/Area/ Volume M-Mode: Depth, Distance, HR PWD (Manual): Velocity, Velocity Pairs, RI, Accl, S/D, A/B, PI, HR/ PWD (AutoTrace: RI, PI, Accl, S/D, HR, AT, TAMX and TAMN	Same	Same
Principle of Operation	Applying high voltage burst to the Piezoelectric material in the transducer and detect reflected echo to construct the diagnostic image	Same	Same
Acoustic Output	Track 3:MI, TIS, TIC, TIB (TI Range 0-6.0) Derated I_{SPTA}: 720mW/cm^2 maximum, Mechanical Index ≤ 1.9 maximum or Derated I_{SPPA} ≤ 190 W/cm^2 max Ophthalmic use: TI = Max (TIS_as, TIC) ≤ 1; ISPTA.3 ≤ 50mW/cm2; and MI ≤ 0.23	Same	Same
Transducer Types	Linear Array Curved Linear Array Phased Array Trans-esophageal Pencil Probe Intracavitary	Same	Same
Transducer Frequency	1.0 – 20.0 MHz	Same	1.0 – 14.0 MHz
DICOM Compliant	Yes	Same	Same
Special Procedures User Interface	Yes	Same	Same
Display Monitor/ Monitor Arm	ZS3: Color 19" Liquid Crystal Display (LCD)/ 2 arm articulation plus tilt and swivel z.one $_{pro}$: Color 17" Liquid Crystal Display (LCD)/ Tilt and swivel	Color 19" Liquid Crystal Display (LCD)/ 2 arm articulation plus tilt and swivel	Cart: Same Scan Engine: 5.8" Liquid Crystal Display (LCD)
Scanner	Integrated	Same	Portable
Transducer Port(s)	Multi-Transducer Port (Three)	Same	Cart: same Scanner/ Scan Module: One
Dimensions/ Weight	Height, max (in operational use) 157.5cm (62in) Height, min (in operational use) 128cm (50.5in) Height min (displayed lower for transport) 104cm (41in) Width: 51cm (21.1in) Depth: 72cm (28.2) Weight: 65.3kg (144lb)	Same	Cart: Same Scanner/ Scan Module: Height: 7.3cm (2.9in)/ 5.4cm (2.1in) Width: 25.7cm (10.1in)/22.0cm (8.7) Depth: 25cm (9.8in)/ 25cm (9.8in) Weight: 2.5kg (5.6lb)/ 1.6kg (3.5lb)
Power	100-240V options, ~ 50-60Hz, 6A max	Same	same

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Item	ZS3 Ultrasound Platform ZS3 and z.one$_{pro}$ Ultrasound Systems (ZONARE Medical Systems)	ZS3 (ZONARE Medical Systems)	z.one ultra and z.one ultra SP (ZONARE Medical Systems)
Requirements			
Rechargeable Battery	Yes (up to 3.0 hour operation per charge)	Same	same
Wireless Capability	Yes (IEEE 802.11b/g, Wi-Fi compliant)	Same	Same

Summary of Non-Clinical Testing Performed:

The ZS3 and z.one$_{pro}$ Ultrasound Systems were tested in accordance with FDA Guidance Document – Manufacturer's Seeking Clearance for Ultrasound Systems and Transducers. The following testing was completed:

Test	Method	Result
Mechanical Verification	In accordance with device performance specifications	PASS
Electrical Safety	In accordance with IEC 60601-1	PASS
EMC Testing	In accordance with IEC 60601-1-2	PASS
Thermal and Acoustic Output	In accordance with IEC 60601-2-37	PASS
Biocompatibility	In accordance with ISO 10993	PASS
Cleaning & Disinfection	In accordance with FDA Guidance Document	PASS
Software Validation & Verification	In accordance with 62304 and FDA Guidance Document Principles of Software Validation	PASS

NOTE: ZONARE's ZS3 Ultrasound Platform and transducers do not require clinical studies to support the determination of substantial equivalence.

Conclusion

The ZS3 and z.one$_{pro}$ Ultrasound Systems are substantially equivalent in design, intended use, principles of operation, technological characteristics and safety features to ZONARE's ZS3 and z.one ultra Ultrasound Systems. There are no new no new issues of safety and/or effectiveness introduced by the modification proposed when used as instructed.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 18, 2014

ZONARE Medical Systems, Inc.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K141641
Trade/Device Name: ZS3 and z.onepro Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX
Dated: June 17, 2014
Received: June 19, 2014

Dear Mr. Job:

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.

This determination of substantial equivalence applies to the following transducers intended for use with the ZS3 and z.onepro Ultrasound System, as described in your premarket notification:

Transducer Model Number

C4-1	C6-2	C9-3
C10-3	C8-3(3D)	P4-1c
V11-3BE Transducer (off-the-shelf) (Endo-Cavity Transducer E9-3)		
E9-4	E9-3 (3D)	L10-5
L8-3	L14-5sp	L14-5w
L20-5	P8-3TEE	
VF-PM Part #09-2005 (off the shelf) (P9-3ic)		
A2CW	A5CW	

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,

for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K141641

Device Name

ZS3 and z.onepro Ultrasound System

Indications for Use *(Describe)*

The ZS3 and z.onepro 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, 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.

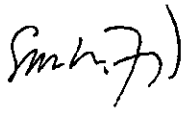
Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*



This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Table 1.3-1: Diagnostic Ultrasound Indications for Use Form – ZONARE's ZS3 and z.one$_{pro}$ Ultrasound System

System:		ZS3 and 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 (Tracks 1 & 3)	B	M	PWD[2]	CWD	Color Doppler[3]	Combined Modes[4]	Other[5,6]
Ophthalmic	Ophthalmic	P		P		P	P	
Fetal Imaging & Other	Fetal	P	P	P	P	P	P	P[5]
	Abdominal	P	P	P	P	P	P	P[5]
	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	P[5]
	Small Organ (Thyroid, Breast, Testes, etc.)	P	P	P		P	P	P[5,8]
	Neonatal Cephalic	P	P	P	P	P	P	P[5]
	Adult Cephalic	P	P	P	P	P	P	P[5]
	Trans-rectal	P	P	P		P	P	P[5]
	Trans-vaginal	P	P	P		P	P	P[5]
	Trans-urethral							
	Trans-esoph. (non-Card.)	P	P	P	P	P	P	P[5]
	Musculo-skel. (Conventional)	P	P	P		P	P	P[5,8]
	Musculo-skel. (Superficial)	P	P	P		P	P	P[5,8]
	Intravascular							
	Other (3D/4D and Contrast)	P	P	P		P	P	
Cardiac	Cardiac Adult	P[1]	P	P	P	P	P	P[5]
	Cardiac Pediatric	P	P	P	P	P	P	P[5]
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)	P	P	P	P	P	P	P[5]
	Intra-cardiac	P	P	P	N	P	N	
	Other (3D/4D)	P	P	P	P	P	P	
Peripheral Vessel	Peripheral Vessel	P	P	P	P	P	P	P[5,8]
	Other (3D/4D)	P	P	P		P	P	

N = new system indication; P = previously cleared by FDA 510(k) K101091 or K120703, (St Jude K031066 & K073709) and (Shenzhen Mindray K123185), E=Added under Appendix E

[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+CD, B+PW, B+CD+PW, B+M, M+CM, B+CD+M+CM, B+Elastorgraphy, B+CEUS, and + ECG Trace

[5] Color M-Mode (CM)

[6] Abdominal includes renal, GYN/Pelvic

[7] Intra operative include abdominal, thoracic (cardiac) and vascular (PV)

[8] Freehand tissue elasticity

Prescription Use (Per 21 CFR 801 Subpart D)

Table 1.3-2: Diagnostic Ultrasound Indications for Use Form – Curvilinear Transducer C4-1

System:		ZS3 and z.one$_{ultra}$ 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 (Tracks I Only)	Specific (Track I & III)	B	M	PWD[2]	CWD	Color Doppler[3]	Combined Modes[4]	Other[5,6]
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P	N	P	P	
	Abdominal[8]	P	P	P	N	P	P	
	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-skel. (Conventional)	P	P	P		P		
	Musculo-skel. (Superficial)							
	Intravascular							
	Other (3D/4D and Contrast)	P	P	P		P	P	
Cardiac	Cardiac Adult	P[1]	P	P	N	P	P	
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral Vessel							
	Other (Specify)							

N = new indication; P = previously cleared by FDA 510(k) K101091 & K120703, E=Added under Appendix E

[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+CD, B+PW, B+CD+PW, B+M, M+CM, B+CD+M+CM, B+Elastorgraphy, B+CEUS, and + ECG Trace

[5] Color M-Mode (CM)

[6] Abdominal includes renal, GYN/Pelvic

[7] Intra operative include abdominal, thoracic (cardiac) and vascular (PV)

[8] Freehand tissue elasticity

Prescription Use (Per 21 CFR 801 Subpart D)

Table 1.3-3: Diagnostic Ultrasound Indications for Use Form – Curvilinear Transducer C6-2

System:		ZS3 and 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 (Tracks 1 & 3)	B	M	PWD[2]	CWD	Color Doppler[3]	Combined Modes[4]	Other[5, 8]
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P		P	P	P[1]
	Abdominal[6]	P	P	P		P	P	P[1]
	Intra-operative (Specify)[7]							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	P	P	P		P	P	P[1]
	Small Organ (Thyroid, Breast, Testes, etc.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel (Conventional)							
	Musculo-skel. (Superficial)							
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral Vascular	P	P	P		P	P	P[5]
	Other (Specify)							

N = new indication; P=previously cleared by FDA 510(k) K101091 & K120703, E=Added under Appendix E

[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+CD, B+PW, B+CD+PW, B+M, M+CM, B+CD+M+CM, B+Elastorgraphy, B+CEUS, and + ECG Trace

[5] Color M-Mode (CM)

[6] Abdominal includes renal, GYN/Pelvic

[7] Intra operative include abdominal, thoracic (cardiac) and vascular (PV)

[8] Freehand tissue elasticity

Prescription Use (Per 21 CFR 801 Subpart D)

Table 1.3-4: Diagnostic Ultrasound Indications for Use Form – Curvilinear Transducer C9-3

System:		ZS3 and z.one$_{ultra}$ 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 (Tracks 1 & 3)	B	M	PWD[2]	CWD	Color Doppler[3]	Combined Modes[4]	Other[5,8]
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P		P	P	P[5]
	Abdominal[6]	P	P	P		P	P	P[5]
	Intra-operative (Specify)[7]	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-skel. (Conventional)	P	P	P		P	P	P[5]
	Musculo-skel. (Superficial)	P	P	P		P	P	P[5]
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral Vascular	P	P	P		P	P	P[5]
	Other (Specify)							

N = new indication; P = previously cleared by FDA 510(k) K101091 & K120703; E = Added under Appendix E

[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+CD, B+PW, B+CD+PW, B+M, M+CM, B+CD+M+CM, B+Elastorgraphy, B+CEUS, and + ECG Trace

[5] Color M-Mode (CM)

[6] Abdominal includes renal, GYN/Pelvic

[7] Intra operative include abdominal and vascular (PV)

[8] Freehand tissue elasticity

Prescription Use (Per 21 CFR 801 Subpart D)

Table 1.3-5: Diagnostic Ultrasound Indications for Use Form – Curvilinear Transducer C10-3

System:		ZS3 and z.one$_{ultra}$ Ultrasound System						
Transducer:		Curvilinear 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)	Specific (Tracks 1 & 3)	B	M	PWD[2]	CWD	Color Doppler[1]	Combined Modes[4]	Other[5,6]
Ophthalmic	Ophthalmic	N		N		N	N	
Fetal Imaging & Other	Fetal	P	P	P	N	P	P	P[5]
	Abdominal[8]	P	P	P	N	P	P	P[5]
	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	N	P	P	P[5]
	Small Organ (Thyroid, Breast, Testes, etc.)							
	Neonatal Cephalic	P	P	P	N	P	P	P[5]
	Adult Cephalic (trans-cranial	P	P	P	N	P	P	P[5]
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult	P	P	P	N	P	P	P[5]
	Cardiac Pediatric	P	P	P	N	P	P	P[5]
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral Vascular	P	P	P	N	P	P	P[5]
	Other (Specify)							

N = new indication; P=previously cleared by the FDA 510(k) K120703, E=Added under Appendix E

[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+CD, B+PW, B+CD+PW, B+M, M+CM, B+CD+M+CM, B+Elastorgraphy, B+CEUS, and + ECG Trace

[5] Color M-Mode (CM)

[6] Abdominal includes renal, GYN Pelvic

[7] Intra operative include abdominal, thoracic (cardiac) and vascular (PV)

[8] Freehand tissue elasticity

Prescription Use (Per 21 CFR 801 Subpart D)

Table 1.3-6: Diagnostic Ultrasound Indications for Use Form – Curvilinear Transducer C8-3(3D)

System:		ZS3 and 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)	Specific (Tracks 1 & 3)	B	M	PWD[2]	CWD	Color Doppler[1]	Combined Modes[4]	Other[5,8]
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P		P	P	P[1]
	Abdominal[6]	P	P	P		P	P	P[1]
	Intra-operative (Specify)[7]							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	P	P	P		P	P	P[1]
	Small Organ (Thyroid, Breast, Testes, etc.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph (non-Card.)							
	Musculo-skel (Conventional)							
	Musculo-skel (Superficial)							
	Intravascular							
	Other (3D/4D)	P	P	P		P	P	P[1]
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral Vascular	P	P	P		P	P	P[1]
	Other (Specify)							

N = new indication; P=previously cleared by FDA 510(k) K101091 & K120703, E=Added under Appendix E

[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+CD, B+PW, B+CD+PW, B+M, M+CM, B+CD+M+CM, B+Elastorgraphy, B+CEUS, and + ECG Trace

[5] Color M-Mode (CM)

[6] Abdominal includes renal, GYN/Pelvic

[7] Intra operative include abdominal, thoracic (cardiac) and vascular (PV)

[8] Freehand tissue elasticity

Prescription Use (Per 21 CFR 801 Subpart D)

Table 1.3-7: Diagnostic Ultrasound Indications for Use Form – Phase (Sector) Array Transducer P4-1c

System:		Z.S3 and z.one$_{ns}$ Ultrasound System						
Transducer:		Phase (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 (Tracks 1 & 3)	B	M	PWD[2]	CWD	Color Doppler[3]	Combined Modes[4]	Other[5,8]
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P	P	P	P	P[1]
	Abdominal[6]	P	P	P	P	P	P	P[1]
	Intra-operative (Specify)[7]							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	P	P	P	P	P	P	P[1]
	Small Organ (Thyroid, Breast, Testes, etc.)							
	Neonatal Cephalic	P	P	P	P	P	P	P[1]
	Adult Cephalic/ trans cranial	P	P	P	P	P	P	P[1]
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult	P[1]	P	P	P	P	P	P[1]
	Cardiac Pediatric	P	P	P	P	P	P	P[1]
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Contrast)	P	P	P		P	P	P[1]
Peripheral Vessel	Peripheral Vascular	P	P	P	P	P	P	P[1]
	Other (Specify)							

N = new indication; P=previously cleared by the FDA 510(k) K101091 or K120703, E=Added under Appendix E

[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+CD, B+PW, B+CD+PW, B+M, M+CM, B+CD+M+CM, B+Elastorgraphy, B+CEUS, and + ECG Trace

[5] Color M-Mode (CM)

[6] Abdominal includes renal, GYN/Pelvic

[7] Intra operative include abdominal, thoracic (cardiac) and vascular (PV)

[8] Freehand tissue elasticity

Prescription Use (Per 21 CFR 801 Subpart D)

Table 1.3-8: Diagnostic Ultrasound Indications for Use Form – Shenzhen Mindray Bio-Medical Electronics Co., Ltd. Model #V11-3BE Transducer (off-the-shelf) (Endo-Cavity Transducer E9-3)

System:		z3 and z.one$_{pro}$ Ultrasound System						
Transducer:		Shenzhen Mindray Bio-Medical Electronics Co., Ltd. Model #V11-3BE Transducer (off-the-shelf) (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 I Only)	Specific (Track I & III)	B	M	PWD[2]	CWD Aux	Color Doppler[1]	Combined Modes[1]	Other[3,4]
Ophthalmic	Ophthalmic							
General application	Fetal	N	N	N		N	N	N[5]
	Abdominal							
	Intra-operative (Specify)[7]							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Thyroid, Breast, Testes, etc.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	N	N	N		N	N	N[5]
	Trans-vaginal	N	N	N		N	N	N[5]
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intravascular							
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral vascular	Peripheral vascular							
	Other (Specify)							

N = new indication; P = previously cleared by FDA Shenzhen Mindray 510(k) K123185, E= Added under Appendix E

[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+CD, B+PW, B+CD+PW, B+M, M+CM, B+CD+M+CM, B+Elastorgraphy, B+CEUS, and + ECG Trace

[5] Color M-Mode (CM)

[6] Abdominal includes renal, GYN/Pelvic

[7] Intra operative include abdominal, thoracic (cardiac) and vascular (PV)

[8] Freehand tissue elasticity

Prescription Use (Per 21 CFR 801 Subpart D)

Table 1.3-9: Diagnostic Ultrasound Indications for Use Form – Endo-Cavity Transducer E9-4

System:		ZS3 and 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 (Tracks 1 & 3)	B	M	PWD[2]	CWD	Color Doppler[3]	Combined Modes[4]	Other[5,8]
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P		P	P	P[5]
	Abdominal							
	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-skel. (Conventional)							
	Musculo-skel (Superficial)							
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-Cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vascular							
	Other (Specify)							

N = new indication; P=previously cleared by FDA 510(k) K101091 & K120703. E=Added under Appendix E

[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+CD, B+PW, B+CD+PW, B+M, M+CM, B+CD+M+CM, B+Elastorgraphy, B+CEUS, and + ECG Trace

[5] Color M-Mode (CM)

[6] Abdominal includes renal, GYN/Pelvic

[7] Intra operative include abdominal, thoracic (cardiac) and vascular (PV)

[8] Freehand tissue elasticity

Prescription Use (Per 21 CFR 801 Subpart D)

Table 1.3-10: Diagnostic Ultrasound Indications for Use Form – Endo-Cavity Transducer E9-3 (3D)

System:		ZS3 and z one$_{ge}$ 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 (Tracks 1 & 3)	B	M	PWD[2]	CWD	Color Doppler[3]	Combined Modes[4]	Other[5,6]
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P		P	P	P[5]
	Abdominal							
	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-skel (Conventional)							
	Musculo-skel (Superficial)							
	Intravascular							
	Other (3D/4D)	P	P	P		P	P	P[5]
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vascular							
	Other (Specify)							

N = new indication; P=previously cleared by FDA 510(k) K101091 & K120703, E=Added under Appendix E

[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+CD, B+PW, B+CD+PW, B+M, M+CM, B+CD+M+CM, B+Elastorgraphy, B+CEUS, and + ECG Trace

[5] Color M-Mode (CM)

[6] Abdominal includes renal, GYN/Pelvic

[7] Intra operative include abdominal, thoracic (cardiac) and vascular (PV)

[8] Freehand tissue elasticity

Prescription Use (Per 21 CFR 801 Subpart D)

Table 1.3-11: Diagnostic Ultrasound Indications for Use Form – Linear Transducer L10-5

System:		ZS3 and z.one$_{ultra}$ 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 (Tracks 1 & 3)	B	M	PWD[2]	CWD	Color Doppler[3]	Combined Modes[4]	Other[5,6]
Ophthalmic	Ophthalmic	P		P		P	P	
Fetal Imaging & Other	Fetal	P	P	P		P	P	P[5]
	Abdominal[8]	P	P	P		P	P	P[5]
	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[5,9]
	Neonatal Cephalic	P	P	P		P	P	P[5]
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Conventional)	P	P	P		P	P	P[5,6]
	Musculo-skel. (Superficial)	P	P	P		P	P	P[5,6]
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral Vascular	P	P	P		P	P	P[5,6]
	Other (Specify)							

N = new indication; P = previously cleared by the FDA 510(k) K101091 & K120703, E= Added under Appendix E

[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+CD, B+PW, B+CD+PW, B+M, M+CM, B+CD+M+CM, B+Elastorgraphy, B+CEUS, and + ECG Trace

[5] Color M-Mode (CM)

[6] Abdominal includes renal, GYN/Pelvic

[7] Intra operative include abdominal, thoracic (cardiac) and vascular (IV)

[8] Freehand tissue elasticity

Prescription Use (Per 21 CFR 801 Subpart D)

Table 1.3-12: Diagnostic Ultrasound Indications for Use Form – Linear Transducer L8-3

System:		z.S3 and 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 I Only)	Specific (Tracks 1 & 3)	B	M	PWD[2]	CWD	Color Doppler[3]	Combined Modes[4]	Other[5,6]
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P		P	P	P[5]
	Abdominal[6]	P	P	P		P	P	P[5]
	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[5,8]
	Neonatal Cephalic	P	P	P		P	P	P[5]
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Conventional)	P	P	P		P	P	P[5,8]
	Musculo-skel (Superficial)	P	P	P		P	P	P[5,8]
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral Vascular	P	P	P		P	P	P[5,8]
	Other (Specify)							

N = new indication; P=previously cleared by the FDA 510(k) K101091 & K120703, E=Added under Appendix E

[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+CD, B+PW, B+CD+PW, B+M, M+CM, B+CD+M+CM, B+Elastorgraphy, B+CEUS, and + ECG Trace

[5] Color M-Mode (CM)

[6] Abdominal includes renal, GYN/Pelvic

[7] Intra operative include abdominal, thoracic (cardiac) and vascular (PV)

[8] Freehand tissue elasticity

Prescription Use (Per 21 CFR 801 Subpart D)

Table 1.3-13: Diagnostic Ultrasound Indications for Use Form – Linear Transducer L14-5sp

System:		ZS3 and z one$_{m,...}$ 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[5, 8]
Ophthalmic	Ophthalmic	N		N		N	N	
Fetal Imaging & Other	Fetal	P	P	P		P	P	P[5]
	Abdominal[6]	P	P	P		P	P	P[5]
	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, 8]
	Neonatal Cephalic	P	P	P		P	P	P[5]
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Conventional)	P	P	P		P	P	P[5, 8]
	Musculo-skel (Superficial)	P	P	P		P	P	P[5, 8]
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral Vascular	P	P	P		P	P	P[5, 8]
	Other (Specify)							

N = new indication; P=previously cleared by the FDA 510(k) K101091 & K120703. E=Added under Appendix E

[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+CD, B+PW, B+CD+PW, B+M, M+CM, B+CD+M+CM, B+Elastorgraphy, B+CEUS, and + ECG Trace

[5] Color M-Mode (CM)

[6] Abdominal includes renal, GYN/Pelvic

[7] Intra operative include abdominal, thoracic (cardiac) and vascular (PV)

[8] Freehand tissue elasticity

Prescription Use (Per 21 CFR 801 Subpart D)

Table 1.3-14: Diagnostic Ultrasound Indications for Use Form – Linear Transducer L14-5w

System:		ZS3 and 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 (Tracks 1 & 3)	B	M	PWD[2]	CWD	Color Doppler[3]	Combined Modes[4]	Other[5,8]
Ophthalmic	Ophthalmic	N		N		N	N	
Fetal Imaging & Other	Fetal	P	P	P		P	P	P[5]
	Abdominal[6]	P	P	P		P	P	P[5]
	Intra-operative (Specify)	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[5,8]
	Neonatal Cephalic	P	P	P		P	P	P[5]
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Conventional)	P	P	P		P	P	P[5,8]
	Musculo-skel. (Superficial)	P	P	P		P	P	P[5,8]
	Intravascular (Cardiac)							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral Vascular	P	P	P		P	P	P[5,8]
	Other (Specify)							

N = new indication; P=previously cleared by the FDA 510(k) K101091 & K120703, E=Added under Appendix E

[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+CD, B+PW, B+CD+PW, B+M, M+CM, B+CD+M+CM, B+Elastorgraphy, B+CEUS, and + ECG Trace

[5] Color M-Mode (CM)

[6] Abdominal includes renal, GYN Pelvic

[7] Intra operative include abdominal, thoracic (cardiac) and vascular (PV)

[8] Freehand tissue elasticity

Prescription Use (Per 21 CFR 801 Subpart D)

Table 1.3-15: Diagnostic Ultrasound Indications for Use Form – Linear Transducer L20-5

System:		ZS3 and z.one$_{ultra}$ 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 (Tracks 1 & 3)	B	M	PWD[2]	CWD	Color Doppler[3]	Combined Modes[4]	Other[5,8]
Ophthalmic	Ophthalmic	N		N		N	N	
Fetal Imaging & Other	Fetal	E	E	E		E	E	E[5]
	Abdominal[6]	E	E	E		E	E	E[5]
	Intra-operative (Specify)[7]	E	E	E		E	E	E[5]
	Intra-operative (Neuro)	E		E		E	E	E[5]
	Laparoscopic							
	Pediatric	E	E	E		E	E	E[5]
	Small Organ (Thyroid, Breast, Testes, etc.)	E	E	E		E	E	E[5,8]
	Neonatal Cephalic	E	E	E		E	E	E[5]
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel (Conventional)	E	E	E		E	E	E[5,8]
	Musculo-skel. (Superficial)	E	E	E		E	E	E[5,8]
	Intravascular							
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral Vascular	E	E	E		E	E	E[5,8]
	Other (Specify)							

N = new indication, P=previously cleared by the FDA, E= Added under Appendix E

[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+CD, B+PW, B+CD+PW, B+M, M+CM, B+CD+M+CM, B+Elastorgraphy, B+CEUS, and + ECG Trace

[5] Color M-Mode (CM)

[6] Abdominal includes renal, GYN/Pelvic

[7] Intra operative include abdominal, thoracic (cardiac) and vascular (PV)

[8] Freehand tissue elasticity

Prescription Use (Per 21 CFR 801 Subpart D)

Table 1.3-15: Diagnostic Ultrasound Indications for Use Form – Trans-esophageal Transducer P8-3TEE

System:		ZS3 and z.one$_{ee}$ Ultrasound System						
Transducer:		Trans-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 (Tracks 1 & 3)	B	M	PWD[2]	CWD	Color Doppler[1]	Combined Modes[4]	Other[5,8]
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	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-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)	P	P	P	P	P	P	P[5]
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral Vessel							
	Other (Specify)							

N = new indication; P=previously cleared by FDA 510(k) K101091 & K120703, E=Added under Appendix E

[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+CD, B+PW, B+CD+PW, B+M, M+CM, B+CD+M+CM, B+Elastorgraphy, B+CEUS, and + ECG Trace

[5] Color M-Mode (CM)

[6] Abdominal includes renal, GYN/Pelvic

[7] Intra operative include abdominal, thoracic (cardiac) and vascular (PV)

[8] Freehand tissue elasticity

Prescription Use (Per 21 CFR 801 Subpart D)

Table 1.3-16: Diagnostic Ultrasound Indications for Use Form – St. Jude EP ViewFlex PLUS ICE Catheter model # VF-PM Part #09-2005 (off the shelf) (P9-3ic)

System:		ZS3 and z.one$_{ep}$ Ultrasound System						
Transducer:		St. Jude EP ViewFlex PLUS ICE Catheter model # VF-PM Part #09-2005 (off the shelf) (P9-3ic)						
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 (Tracks 1 & 3)	B	M	PWD[2]	CWD	Color Doppler[3]	Combined Modes[4]	Other[5,8]
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	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-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac	P	P	P	N	P	N	
	Other (Specify)							
Peripheral Vessel	Peripheral vascular							
	Other (Specify)							

N – new indication; P –previously cleared by FDA 510(k) K101091 & K120703, (St Jude K031066 & K073709); E–Added under Appendix E

[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+CD, B+PW, B+CD+PW, B+M, M+CM, B+CD+M+CM, B+Elastorgraphy, B+CEUS, and + ECG Trace

[5] Color M-Mode (CM)

[6] Abdominal includes renal, GYN/Pelvic

[7] Intra operative include abdominal, thoracic (cardiac) and vascular (PV)

[8] Freehand tissue elasticity

Prescription Use (Per 21 CFR 801 Subpart D)

Table 1.3-17: Diagnostic Ultrasound Indications for Use Form – A2CW (Common name Pencil Probe)

System:		ZS3 and z.one$_{ap}$ 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 (Tracks 1 & 3)	B	M	PWD[2]	CWD	Color Doppler[3]	Combined Modes[4]	Other[5,6]
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	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-skel (Conventional)							
	Musculo-skel (Superficial)							
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult				P			
	Cardiac Pediatric				P			
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vascular							
	Other (Specify)							

N = new indication; P=previously cleared by FDA 510(k) K101091; E=Added under Appendix E

[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+CD, B+PW, B+CD+PW, B+M, M+CM, B+CD+M+CM, B+Elastorgraphy, B+CEUS, and + ECG Trace

[5] Color M-Mode (CM)

[6] Abdominal includes renal, GYN/Pelvic

[7] Intra operative include abdominal, thoracic (cardiac) and vascular (PV)

[8] Freehand tissue elasticity

Prescription Use (Per 21 CFR 801 Subpart D)

Table 1.3-18: Diagnostic Ultrasound Indications for Use Form – A5CW (Common name Pencil Probe)

System:		Z83 and 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 (Tracks 1 & 3)	B	M	PWD[2]	CWD	Color Doppler[3]	Combined Modes[4]	Other[5,8]
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	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-skel (Conventional)							
	Musculo-skel. (Superficial)							
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral Vascular				P			
	Other (Specify)							

N – new indication, P -previously cleared by FDA 510(K) K101091; E--Added under Appendix E

[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+CD, B+PW, B+CD+PW, B+M, M+CM, B+CD+M+CM, B+Elastorgraphy, B+CEUS, and + ECG Trace

[5] Color M-Mode (CM)

[6] Abdominal includes renal, GYN/Pelvic

[7] Intra operative include abdominal, thoracic (cardiac) and vascular (PV)

[8] Freehand tissue elasticity

Prescription Use (Per 21 CFR 801 Subpart D)