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

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

May 15, 2015

Re: K151175
Trade/Device Name: ZS3 and z.one$_{pro}$ Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX
Dated: April 30, 2015
Received: May 1, 2015

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.

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

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Robert Ochs, Ph.D.
Acting 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.

(k) Number *(if known)*

K151175

Device Name

ZS3and 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/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.

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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Food and Drug Administration
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"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."

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.

10(k) Number *(if known)*

Device Name

System: ZS3and z.one$_{pro}$Ultrasound Systems
Transducer: System union of all transducer types

Indications for Use *(Describe)*
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	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)[6]	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) K141641
[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

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)*

Device Name

System: ZS3and z.one$_{pro}$Ultrasound Systems
Transducer: Curvilinear Transducer C4-1

Indications for Use *(Describe)*
Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Tracks 1 Only)	Specific (Track I & III)	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	
	Abdominal[6]	P	P	P	P	P	P	
	Intra-operative (Specify)[7]							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	P	P	P		P	P	
	Pediatric Aux							
	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 (Specify) (3D/4D) contrast	P	P	P		P	P	
Cardiac	Cardiac Adult	P[1]	P	P	P	P	P	
	Cardiac Adult Aux							
	Cardiac Pediatric							
	Cardiac Pediatric Aux							
	Trans-esoph. (Cardiac)							
	Other (specify) 3D/4D							
	Other (intra-cardiac)*							
Peripheral Vessel	Peripheral Vessel							
	Peripheral Vessel Aux							
	Other (Specify) 3D/4D							

N = new indication; P=previously cleared by FDA 510(k) K141641
[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 abdominal, thoracic (cardiac) and vascular (PV)
[8] Freehand tissue elasticity

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)*

Device Name

System: ZS3and z.one$_{pro}$Ultrasound Systems
Transducer: Curvilinear Transducer C6-2

Indications for Use *(Describe)*
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)							
	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)							
	Musculo-skel. (Superficial)							
	Intravascular							
	Other (Specify) (3D/4D)							
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) K141641
[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 abdominal, thoracic (cardiac) and vascular (PV)
[8] Freehand tissue elasticity

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)*

Unknown

Device Name

System: ZS3and z.one$_{pro}$Ultrasound Systems
Transducer: Curvilinear Transducer C9-3

Indications for Use *(Describe)*
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 (Abdominal)	P	P	P		P	P	P[5]
	Intra-operative (Vascular)	P	P	P		P	P	P[5]
	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) (3D/4D)							
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) K141641
[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 abdominal, thoracic (cardiac) and vascular (PV)
[8] Freehand tissue elasticity

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.

)0(k) Number *(if known)*

Device Name

System: ZS3and z.one$_{pro}$Ultrasound Systems
Transducer: Phased (Sector) Array Transducer C10-3

Indications for Use *(Describe)*
Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1)	Specific (Tracks I & III)	B	M	PWD[2]	CWD	Color Doppler[3]	Combined Modes[4]	Other[5, 8]
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]
	Intra-operative (specify)	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/ trans cranial	P	P	P	P	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	P	P	P	P[5]
	Cardiac Pediatric	P	P	P	P	P	P	P[5]
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify) (3D/4D)							
Peripheral Vessel	Peripheral Vascular	P	P	P	P	P	P	P[5]
	Other (Specify) 3D/4D							

N = new indication; P=previously cleared by the FDA 510(k) K141641
[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 abdominal, thoracic (cardiac) and vascular (PV)
[8] Freehand tissue elasticity

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.

0(k) Number *(if known)*

Device Name

System: ZS3and z.one$_{pro}$Ultrasound Systems
Transducer: Curvilinear Transducer C8-3 (3D)

Indications for Use *(Describe)*
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[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)							
	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)							
	Musculo-skel. (Superficial)							
	Intravascular							
	Other (Specify) (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	P	P	P		P	P	P[5]
	Other (Specify)							

N = new indication; P=previously cleared by FDA 510(k) K141641
[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 abdominal, thoracic (cardiac) and vascular (PV)
[8] Freehand tissue elasticity

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.

)0(k) Number *(if known)*

Device Name

System: ZS3and z.one$_{pro}$Ultrasound Systems
Transducer: Phase (Sector) Array Transducer P4-1c

Indications for Use *(Describe)*
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[5]
	Abdominal[6]	P	P	P	P	P	P	P[5]
	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/ trans cranial	P	P	P	P	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[1]	P	P	P	P	P	P[5]
	Cardiac Pediatric	P	P	P	P	P	P	P[5]
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify) (3D/4D)contrast	P	P	P		P	P	P[5]
Peripheral Vessel	Peripheral Vascular	P	P	P	P	P	P	P[5]
	Other (Specify)							

N = new indication; P=previously cleared by the FDA 510(k) K141641
[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 abdominal, thoracic (cardiac) and vascular (PV)
[8] Freehand tissue elasticity

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Indications for Use

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

10(k) Number *(if known)*

Device Name

System: ZS3and z.one$_{pro}$Ultrasound Systems
Transducer: Shenzhen Mindray Bio-Medical Electronics Co., Ltd. Model #V11-3BE Transducer (off-the-shelf) (Endo-Cavity Transducer E9-3)

Indications for Use *(Describe)*
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	Color Doppler[3]	Combined Modes[4]	Other[5, 8]
Ophthalmic	Ophthalmic							
General application	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) (3D/4D)							
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 510(k) K141641
[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 abdominal, thoracic (cardiac) and vascular (PV)
[8] Freehand tissue elasticity

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10(k) Number *(if known)*

Device Name

System: ZS3and z.one$_{pro}$Ultrasound Systems
Transducer: Endo-Cavity Transducer E9-4

Indications for Use *(Describe)*
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) (3D/4D)							
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) K141641
[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 abdominal, thoracic (cardiac) and vascular (PV)
[8] Freehand tissue elasticity

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Indications for Use

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

)0(k) Number *(if known)*

Device Name

System: ZS3and z.one$_{pro}$Ultrasound Systems
Transducer: Endo-Cavity Transducer E9-3 (3D)

Indications for Use *(Describe)*
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) (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) K141641
[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 abdominal, thoracic (cardiac) and vascular (PV)
[8] Freehand tissue elasticity

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.

)0(k) Number *(if known)*

Device Name

System: ZS3and z.one$_{pro}$Ultrasound Systems
Transducer: Linear Transducer L10-5

Indications for Use *(Describe)*
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, 8]
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]
	Intra-operative (Specify)[7]	P	P	P		P	P	P[5]
	Intra-operative (Neuro)	P		P		P	P	P[5]
	Laparoscopic							
	Pediatric	P	P	P		P	P	P[5]
	Small Organ (Thyroid, Breast, Testes, etc.)	P	P	P		P	P	P[5] P[8]
	Neonatal Cephalic	P	P	P		P	P	P[5]
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Conventional)	P	P	P		P	P	P[5, 8]
	Musculo-skel. (Superficial)	P	P	P		P	P	P[5, 8]
	Intravascular							
	Other (Specify)[8] (3D/4D)							
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] P[8]
	Other (Specify) 3D/4D							

N = new indication; P=previously cleared by the FDA 510(k) K141641
[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 abdominal, thoracic (cardiac) and vascular (PV)
[8] Freehand tissue elasticity

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Indications for Use

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

10(k) Number *(if known)*

Device Name

System: ZS3and z.one$_{pro}$Ultrasound Systems
Transducer: Linear Transducer L8-3

Indications for Use *(Describe)*
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, 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)	P		P		P	P	P[5]
	Laparoscopic							
	Pediatric	P	P	P		P	P	P[5]
	Small Organ (Thyroid, Breast, Testes, etc.)	P	P	P		P	P	P[5] P[8]
	Neonatal Cephalic	P	P	P		P	P	P[5]
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Conventional)	P	P	P		P	P	P[5, 8]
	Musculo-skel. (Superficial)	P	P	P		P	P	P[5, 8]
	Intravascular							
	Other (Specify)[8] 3D/4D							
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] P[8]
	Other (Specify) 3D/4D							

N = new indication; P=previously cleared by the FDA 510(k) K141641
[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 abdominal, thoracic (cardiac) and vascular (PV)
[8] Freehand tissue elasticity

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Indications for Use

Form Approved: OMB No. 0910-0120
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See PRA Statement below.

)0(k) Number *(if known)*

Device Name

System: ZS3and z.one$_{pro}$Ultrasound Systems
Transducer: Linear Transducer L14-5sp

Indications for Use *(Describe)*
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	P		P		P	P	
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] P[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)[8] 3D/4D							
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] P[8]
	Other (Specify) 3D/4D							

N = new indication; P=previously cleared by the FDA 510(k) K141641
[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 abdominal, thoracic (cardiac) and vascular (PV)
[8] Freehand tissue elasticity

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Indications for Use

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

10(k) Number *(if known)*

Device Name

System: ZS3and z.one$_{pro}$Ultrasound Systems
Transducer: Linear Transducer L14-5w

Indications for Use *(Describe)*
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	P		P		P	P	
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] P[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)[8] 3D/4D							
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] P[8]
	Other (Specify) 3D/4D							

N = new indication; P=previously cleared by the FDA 510(k) K141641
[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 abdominal, thoracic (cardiac) and vascular (PV)
[8] Freehand tissue elasticity

DEPARTMENT OF HEALTH AND HUMAN SERVICES
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Indications for Use

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

510(k) Number *(if known)*

Device Name

System: ZS3and z.one$_{pro}$Ultrasound Systems
Transducer: Linear Transducer L20-5

Indications for Use *(Describe)*
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	P		P		P	P	
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] P[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)[8] 3D/4D							
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] P[8]
	Other (Specify) 3D/4D							

N = new indication; P=previously cleared by the FDA 510(k) K141641
[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 abdominal, thoracic (cardiac) and vascular (PV)
[8] Freehand tissue elasticity

DEPARTMENT OF HEALTH AND HUMAN SERVICES
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Indications for Use

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

)0(k) Number *(if known)*

Device Name

System: ZS3and z.one$_{pro}$Ultrasound Systems
Transducer: Tran-Esophageal Transducer: P8-3TEE

Indications for Use *(Describe)*
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.)	P	P	P	P	P	P	P[5]
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intravascular							
	Other (Specify) (3D/4D)							
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) K141641
[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 abdominal, thoracic (cardiac) and vascular (PV)
[8] Freehand tissue elasticity

DEPARTMENT OF HEALTH AND HUMAN SERVICES
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Indications for Use

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

)0(k) Number *(if known)*

Device Name

System: ZS3and z.one$_{pro}$Ultrasound Systems
Transducer: St. Jude EP ViewFlex PLUS ICE Catheter model # VF-PM Part #09-2005 (off the shelf) (P9-3ic)

Indications for Use *(Describe)*
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) (3D/4D)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)	P	P	P	P	P	P	
Peripheral Vessel	Peripheral vascular							
	Other (Specify)							

N = new indication; P=previously cleared by FDA 510(k) K141641, St Jude K031066 & K073709;
[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 abdominal, thoracic (cardiac) and vascular (PV)
[8] Freehand tissue elasticity

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Indications for Use

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

10(k) Number *(if known)*

Device Name

System: ZS3and z.one$_{pro}$Ultrasound Systems
Transducer: A2CW (Common name Pencil Probe)

Indications for Use *(Describe)*
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							
	Intra-luminal							
	Other (Specify) (3D/4D)							
Cardiac	Cardiac Adult				P			
	Cardiac Pediatric				P			
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Intra-Cardiac)							
Peripheral Vessel	Peripheral vascular							
	Other (Specify)							

N = new indication; P=previously cleared by FDA 510(k) K141641
[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 abdominal, thoracic (cardiac) and vascular (PV)
[8] Freehand tissue elasticity

DEPARTMENT OF HEALTH AND HUMAN SERVICES
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Indications for Use

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

)0(k) Number *(if known)*

Device Name

System: ZS3and z.one$_{pro}$Ultrasound Systems
Transducer: A5CW (Common name Pencil Probe)

Indications for Use *(Describe)*
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) (3D/4D)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Intra-Cardiac)							
Peripheral Vessel	Peripheral vascular				P			
	Other (Specify)							

N = new indication; P=previously cleared by FDA 510(k) K141641
[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 abdominal, thoracic (cardiac) and vascular (PV)
[8] Freehand tissue elasticity

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.

10(k) Number *(if known)*

Device Name

System: ZS3and z.one$_{pro}$Ultrasound Systems
Transducer: Curvilinear Transducer C9-3sp

Indications for Use *(Describe)*
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	Color Doppler[3]	Combined Modes[4]	Other[5, 8]
Ophthalmic	Ophthalmic							
General application	Fetal	N	N	N		N	N	N[5]
	Abdominal	N	N	N		N	N	N[5]
	Intra-operative (Abdominal)[7]	N	N	N		N	N	N[5]
	Intra-operative (Vascular)	N	N	N		N	N	N[5]
	Laparoscopic							
	Pediatric	N	N	N		N	N	N[5]
	Small Organ (Thyroid, Breast, Testes, etc.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Conventional)	N	N	N		N	N	N[5]
	Musculo-skel. (Superficial)	N	N	N		N	N	N[5]
	Intravascular							
	Other (Specify) (3D/4D)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral vascular	Peripheral vascular	N	N	N		N	N	N[5]
	Other (Specify)							

N = new indication; P=previously cleared by FDA 510(k) K141641
[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)
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[8] Freehand tissue elasticity

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:	Steve Geerdes Director QA/RA Phone: (650) 316-3106 Facsimile: (650) 967-9056 E-mail: sgeerdes@zonare.com		
Date Prepared:	Revised May 14, 2015		
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		K150249

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

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 Ultrasound platform (ZONARE Medical Systems)
510(k) Number	Current Submission	K150249
Intended Use	Diagnostic ultrasound imaging or fluid flow analysis of the human body.	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
Design	Diagnostic zone technology ultrasound based platform	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
Patient Contact Materials	Complies with ISO 10993	Same (However, two materials have been added to E9-4 transducer. Momentive RTV162 silicones and Loctite K64481 = Hysol M21-HP colored light gray). Both found to comply with ISO 10993
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	Same

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Item	ZS3 Ultrasound Platform ZS3 and z.one *pro* Ultrasound Systems (ZONARE Medical Systems)	ZS3 Ultrasound platform (ZONARE Medical Systems)
	B+CD, B+PW, 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
Principle of Operation	Applying high voltage burst to the Piezoelectric material in the transducer and detect reflected echo to construct the diagnostic image	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
Transducer Types	Linear Array Curved Linear Array Phased Array Trans-esophageal Pencil Probe Intracavitary	Same
Transducer Frequency	1.0 – 20.0 MHz	Same
DICOM Compliant	Yes	Same
Special Procedures User Interface	Yes	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	Same
Scanner	Integrated	Same
Transducer Port(s)	Multi-Transducer Port (Three)	Same
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
Power Requirements	100-240V options, ~ 50-60Hz, 6A max	Same
Rechargeable Battery	Yes (up to 3.0 hour operation per charge)	Same
Wireless	Yes (IEEE 802.11b/g, Wi-Fi compliant)	Same

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Item	ZS3 Ultrasound Platform ZS3 and z.one *pro* Ultrasound Systems (ZONARE Medical Systems)	ZS3 Ultrasound platform (ZONARE Medical Systems)
Capability		

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 platform system and (Software and Hardware) remain unchanged from the last 510k clearance K150249. The only change with this submission is the addition of new patient contacting materials Listed in comparison chart above. The two materials have been added to E9-4 transducer. Momentive RTV162 silicones and Loctite K64481 = Hysol M21-HP colored light gray). Both found to comply with ISO 10993. 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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