

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

May 15, 2015

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

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

<u>http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm</u> 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 A Ochs

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

Indications for Use

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

Type of Use (Select one or both, as applicable) Prescription Use (Part 21 CFR 801 Subpare)	rt D) Over-The-Counter Use (21 CFR 801 Subpart C)
)	
Fetal/obstetric, gynecological; Abdominal (renal, GYN/Pelv. neurological; Pediatric; small organ (thyroid, breast, testes, e	r use by a qualified physician for ultrasound evaluation of Ophthalmic; ic; Intra-operative (abdominal, thoracic, and vascular), Intra-operative (co., Adult & Neonatal Cephalic; Trans-rectal, Trans-vaginal, Trans-cranial, (conventional & superficial); 3D/4D; Cardiac - Adult/ Pediatric/ Fetal; ssue and contrast imaging and Tissue elasticity.
Indications for Use (Describe)	
ZS3and z.one _{pro} Ultrasound Systems	
Device Name	
K151175	
(k) Number (<i>if known</i>) K151175	

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.

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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."

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: ZS3 and 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 Applicatio	n y a said a said a		100000		Mode of	Operation		
General (Track 1 Only)	Specific (Tracks 1 & 3)	В	М	PWD ²	CWD	Color Doppler ³	Combined Modes ⁴	Other ^{5, 8}
Ophthalmic	Ophthalmic	P	T	P		P	P	12.5
	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	Ĭ				Ī		
	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
Datal Taraniana 0.	Adult Cephalic	P	P	P .	P	P	P	P 5
Fetal Imaging & Other	Trans-rectal	P	P	P		P	P	P 5
Ottlei	Trans-vaginal	P	P	P		P	P	P 5
	Trans-urethral							
	Trans-esoph, (non- Card.)	P	P	Р	Р	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	р	Р		P	P	
· · · · · · · · · · · · · · · · · · ·	Cardiac Adult	P1	P	P	P	P	P	P 5
	Cardiac Pediatric	P	P	P	P	P	P	P ³
Contin	Intravascular (Cardiac)				#			
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	P	P	Р	P	P	P	P 5,8
Peripheral Vessel	Other (3D/4D)	Р	.P	Р		P	Р	

N = new system indication; P = previously cleared by FDA 510(k) K141641

2 OF 21

Includes B-Mode and Harmonic (contrast) imaging (HI)
 Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)

Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)

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 (cardiae) and vascular (PV)

⁸ Freehand tissue elasticity

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)

Clinical Applicatio	n a la l	Mode	of Opera	ion	erance in	and Car		14.44.4
General	Specific	В	М	PWD ²	CWD	Color	Combined	Other ^{5,8}
(Tracks 1 Only)	(Track I & III)		111	1 ,,,,,,,,		Doppler ³	Modes ⁴	
Ophthalmic	Ophthalmic		<u> </u>			<u> </u>	-	
	Fetal	P	P	P	P	P	P	
	Abdominal ⁶	P	P	P	P	Р	P	
	Intra-operative (Specify) ⁷				<u> </u>			
	Intra-operative (Neuro)							
	Laparoscopic			<u> </u>				
	Pediatric	P	P	P		P	P	
	Pediatric Aux							
	Small Organ (Thyroid,							}
	Breast, Testes, etc.)							<u> </u>
	Neonatal Cephalic							
	Adult Cephalic							
Fetal Imaging &	Trans-rectal						Ì.	
Other	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-							
	Card.)					<u> </u>		
	Musculo-skel.	P	Р	P		P		1
	(Conventional)	Г	F	1		*		
	Musculo-skel.				1			
	(Superficial)				<u> </u>			ļ
	Intravascular	<u> </u>	ļ .					<u> </u>
	Other (Specify)							
	Other (Specify) (3D/4D)	р	l _P	P		P	l p	
	contrast	r	1	1		1	1	
		.,		<u> </u>				
	Cardiac Adult	P ¹	P	P	P	P	P	ļ
	Cardiac Adult Aux							
	Cardiac Pediatric						ļ	
Cardiac	Cardiac Pediatric Aux						ļ	ļ
	Trans-esoph. (Cardiac)							
	Other (specify) 3D/4D							
	Other (intra-cardiac)*							
<u> </u>	Peripheral Vessel							
Peripheral Vessel	Peripheral Vessel Aux							
A OLIPHOLIE T OSSOL	Other (Specify) 3D/4D					<u> </u>	<u> </u>	
	P=previously cleared by FDA	#10/1\ '	7141741	1	<u> </u>		<u>. </u>	1

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

Indications for Use

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

ัจ10(k) Number (if known)

Device Name

System: ZS3and z.one_{pro}Ultrasound Systems Transducer: Curvilinear Transducer C6-2

Indications for Use (Describe)

Clinical Application	n di di di di	Mode	of Operat	ion	水质编制器			no distil
General (Track I Only)	Specific (Tracks 1 & 3)	В	M	PWD²	CWD	Color Doppler ³	Combined Modes ⁴	Other5,8
Ophthalmic	Ophthalmic			I I				
	Fetal	P	P	P	_	P	P	P ⁵
	Abdominal ⁶	P	P	P		P	P	P ⁵
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic						<u> </u>	
	Pediatric	P	P	P	<u> </u>	P	P	P ⁵
	Small Organ (Thyroid, Breast, Testes, etc.)		-					
	Neonatal Cephalic			-				
Fetal Imaging &	Adult Cephalic		ļ					
Other Trans-rect			+	1			 	
	Trans-vaginal			-				
	Trans-urethral		+	1		<u> </u>		
	Trans-esoph. (non- Card.)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)					1		-
	Intravascular							
	Other (Specify) (3D/4D)							
	Cardiac Adult							
	Cardiac Pediatric							
Cardiac	Intravascular (Cardiac)							
Cardiac	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
D : 1 131 1	Peripheral Vascular	P	P	P		P	P	P^5
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)

Abdominal includes renal, GYN/Pelvic

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

⁸ Freehand tissue elasticity

Indications for Use

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

\$10(k) Number (if known)

Unknown

Device Name

System: ZS3 and z.onepro Ultrasound Systems Transducer: Curvilinear Transducer C9-3

Indications for Use (Describe)

Clinical Application	n	Mode	of Opera	ion		2014年慶和	The Administration	
General (Track 1 Only)	Specific (Tracks 1 & 3)	В	М	PWD ²	CWD	Color Doppler ³	Combined Modes ⁴	Other ^{5, 8}
Ophthalmic	Ophthalmic							
	Fetal	P	P	P		P	P	P ⁵
	Abdominal ⁶	P	P	P		P	P	P ⁵
	Intra-operative (Abdominal)	P	P	P		Р	P	P ⁵
	Intra-operative (Vascular)	P	Р	P		Р	P	P ⁵
	Laparoscopic					<u> </u>	<u> </u>	7.5
	Pediatric	Р	P	P		P	P	P ⁵
	Small Organ (Thyroid, Breast, Testes, etc.)		<u> </u>					
The Street land Or	Neonatal Cephalic							
Fetal Imaging & Other	Adult Cephalic					<u></u>		
Other	Trans-rectal		<u> </u>					
	Trans-vaginal							
	Trans-urethral		<u> </u>					
	Trans-esoph. (non- Card.)							
	Musculo-skel. (Conventional)	P	P	Р		P	P	P ⁵
	Musculo-skel. (Superficial)	P	P	Р		Р	Р	P ⁵
	Intravascular							
	Other (Specify) (3D/4D)							
	Cardiac Adult						<u></u>	
	Cardiac Pediatric							
01'	Intravascular (Cardiac)							
Cardiac	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							<u> </u>
	Peripheral Vascular	P	P	P		P	P	P ⁵
Peripheral Vessel	Other (Specify)			<u></u>			<u> </u>	

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

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)

Clinical Applicatio	n ča e s s s s s s s s s s s s s s s s s s	Mode	of Operat	ion				
General (Track 1)	Specific (Tracks I & III)	В	М	PWD ²	CWD	Color Doppler ³	Combined Modes ⁴	Other ^{5, 8}
Ophthalmic	Ophthalmic	P		P		P	P	
	Fetal	Р	P	P	P	P	P	P ⁵
	Abdominal ⁶	P	Р	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
Fetal Imaging &	Adult Cephalic/ trans cranial	Р	P	P	P	P	P	P⁵
Other	Trans-rectal		T					
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non- Card.)							
-	Musculo-skel. (Conventional)							i
	Musculo-skel. (Superficial)							
	Intravascular							
	Other (Specify)							
·	Cardiac Adult	P	P	P	p	P	P	P ⁵
	Cardiac Pediatric	P	P	P	P	P	P	P ⁵
	Intravascular (Cardiac)			l				
Cardiac	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify) (3D/4D)							
	Peripheral Vascular	P	P	P.	P	P	P	P ⁵
Peripheral Vessel	Other (Specify) 3D/4D							<u> </u>

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

-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: ZS3 and z.onepro Ultrasound Systems Transducer: Curvilinear Transducer C8-3 (3D)

Indications for Use (Describe)

Clinical Application	n	Mode	of Operat	ion	W. W. W.	张扬·基本示"以	Shight Application	i grana
General (Track 1)	Specific (Tracks 1 & 3)	В	M	PWD²	CWD	Color Doppler ³	Combined Modes ⁴	Other ^{5, 8}
Ophthalmic	Ophthalmic							
	Fetal	P	P	P		P	P	P ⁵
	Abdominal ⁶	P	P	P		P	P	P ⁵
	Intra-operative (Specify)							
	Intra-operative (Neuro)					<u> </u>		
	Laparoscopic							
	Pediatric	P	P	P		P	P	P ⁵
	Small Organ (Thyroid, Breast, Testes, etc.)							_
	Neonatal Cephalic		ļ					
Fetal Imaging &	Adult Cephalic						<u> </u>	<u> </u>
Other	Trans-rectal	<u> </u>						
	Trans-vaginal							
	Trans-urethral						<u> </u>	
	Trans-esoph. (non- Card.)				Ann.			
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)					·		
	Intravascular	-						
	Other (Specify) (3D/4D)	P	P	P		P	P	P ⁵
	Cardiac Adult							ļ
	Cardiac Pediatric							
a "	Intravascular (Cardiac)			<u> </u>				
Cardiac	Trans-esoph. (Cardiac)							<u> </u>
	Intra-cardiac					<u> </u>		
	Other (Specify)					<u> </u>		
	Peripheral Vascular	P	P	P		P	P	P ⁵
Peripheral Vessel	Other (Specify)							<u> </u>

N = new indication; P-previously cleared by FDA 510(k) K141641

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

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)

Clinical Applicatio	H THE RESERVE OF THE PARTY OF T	Mode	of Operat	ion		25人。在一定,曾	MARKET COME	College Bio
General (Track 1 Only)	Specific (Tracks 1 & 3)	В	М	PWD ²	CWD	Color Doppler ³	Combined Modes ⁴	Other ⁵
Ophthalmic	Ophthalmic							
	Fetal	P	P	P	P	P	P	P ⁵
	Abdominal ⁶	P	Р	P	P	P	P	P ⁵
	Intra-operative (Specify)? Intra-operative (Neuro) Laparoscopic Pediatric Small Organ (Thyroid,							
	Intra-operative (Neuro)							
		P	P	P	P	P	P	P ⁵
	Small Organ (Thyroid, Breast, Testes, etc.)							
	Neonatal Cephalic	P	P	P	P	P	P	P ⁵
Fetal Imaging &	Adult Cephalic/ trans cranial	P	P	P	P	P	P	P ⁵
Other	Trans-rectal							
	Trans-vaginal						<u></u>	
	Trans-urethral					1		
	Trans-esoph. (non- Card.)		<u> </u>					
	Musculo-skel. (Conventional)			4.				
	Musculo-skel. (Superficial)							
	Intravascular			l				
	Other (Specify)							
	Cardiac Adult	\mathbf{P}^{1}	P	P	P	P	P	P ⁵
	Cardiac Pediatric	P	P	P	P	P	P	P ⁵
	Intravascular (Cardiac)							
Cardiac	Trans-esoph. (Cardiac)			<u> </u>				
	Intra-cardiac							
	Other (Specify) (3D/4D)contrast	P	P	P		P	P	P ⁵
	Peripheral Vascular	P	P	P	P	P	P	P ⁵
Peripheral Vessel	Other (Specify)							

N = new indication; P=previously cleared by the FDA 510(k) K141641

Includes B-Mode and Harmonic (contrast) imaging (HI)
 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

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.oneproUltrasound 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 o	of Operat	ion				
General	Specific	В	М	PWD ²	CWD	Color	Combined	Other ^{5, 8}
(Track I Only)	(Track I & III)		2.12	1		Doppler ³	Modes ⁴	
Ophthalmic	Ophthalmic							P ⁵
	Fetal	P	P	P		P	P	l P
	Abdominal							
	Intra-operative (Specify) ⁷							ļ <u>.</u>
	Intra-operative (Neuro)							
	Laparoscopic					-	<u> </u>	
	Pediatric							
	Small Organ (Thyroid, Breast, Testes, etc.)							
	Neonatal Cephalic							
	Adult Cephalic	· · · · · · ·					<u> </u>	
General	Trans-rectal	P	P	P		P	Р	P ⁵
application	Trans-vaginal	P	P	P		P	P	P ⁵
,	Trans-urethral						1	
	Trans-esoph. (non-	[ŀ	
	Card.)							ļ
	Musculo-skel.		1					
	(Conventional)		<u> </u>					
	Musculo-skel.							
	(Superficial) Intravascular			_		 	· · · · · · · · · · · · · · · · · · ·	
				 		 	-	
	Other (Specify) (3D/4D)	i						
	Cardiac Adult			 			***	
	Cardiac Pediatric		-		_			
	Intravascular (Cardiac)					 		
Cardiac	Trans-esoph (Cardiac)		1					
	Intra-cardiac	 		†*************************************				
	Other (Specify)	 	 	 		†		
	Peripheral vascular	 	-				<u> </u>	
Peripheral vascular	Other (Specify)	 		1				["
	=nreviously cleared by FDA	61000 P	141641		<u> </u>	1.,		<u> </u>

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

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: ZS3 and z.one_{pro}Ultrasound Systems Transducer: Endo-Cavity Transducer E9-4

Indications for Use (Describe)

Clinical Application		Mode	of Operat	tion 💮 🗎 🖯				100mg (1986)
General	Specific	В	М	PWD ²	CWD	Color	Combined Modes ⁴	Other ^{5, 8}
(Track I Only)	(Tracks 1 & 3)		ļ			Doppler ³	iviodes	
Ophthalmic	Ophthalmic		ļ	4_			-	P ⁵
	Fetal	P	P	P		P	P	P°
	Abdominal							<u> </u>
	Intra-operative (Specify) ⁷							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Thyroid, Breast, Testes, etc.)							
	Neonatal Cephalic							
T . 1	Adult Cephalic		1					
Fetal Imaging & Other	Trans-rectal	P '	P	P		P	P	P ⁵
Otner	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 Adult							
	Cardiac Pediatric						I	
ou ti	Intravascular (Cardiac)							
Cardiac	Trans-esoph. (Cardiac)							
	Intra-Cardiac							
	Other (Specify)							
	Peripheral vascular							
Peripheral Vessel	Other (Specify)							

N = new indication; P=previously cleared by FDA 510(k) K141641

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

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: ZS3 and z.oneproUltrasound Systems Transducer: Endo-Cavity Transducer E9-3 (3D)

Indications for Use (Describe)

Clinical Application		Mode	of Operat	ion	** **********************************			
General	Specific	В	М	PWD^2	CWD	Color	Combined	Other ^{5, 8}
(Track 1 Only)	(Tracks 1 & 3)		141	X 1112	0112	Doppler ³	Modes ⁴	
Ophthalmic	Ophthalmic							P ⁵
	Fetal	Р	P	P		P	P	P,
	Abdominal							
	Intra-operative (Specify) ⁷		<u> </u>					
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							ļ
	Small Organ (Thyroid, Breast, Testes, etc.)							
	Neonatal Cephalic							
	Adult Cephalic							
Fetal Imaging & Other	Trans-rectal	P	P	P		P	P	P ⁵
Other	Trans-vaginal	P	P	P		P	P	P ⁵
	Trans-urethral						<u> </u>	
	Trans-esoph. (non- Card.)							
	Musculo-skel. (Conventional)		-					
	Musculo-skel. (Superficial)	_						
	Intravascular		$\overline{}$	1			1	
	Other (Specify) (3D/4D)	P	P	P		Р	P	P ⁵
	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
Cardiac	Trans-esoph. (Cardiac)		 					
	Intra-cardiac							
	Other (Specify)							
·	Peripheral vascular		1					
Peripheral Vessel	Other (Specify)			1				

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)

Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)

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

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)

Clinical Applicatio	n za	Mode	of Operat	ion 🖖 🖖 🖖	4. 相邻的数			
General (Track I Only)	Specific (Tracks 1 & 3)	В	М	PWD ²	CWD	Color Doppler ³	Combined Modes ⁴	Other ^{5, 8}
Ophthalmic	Ophthalmic	P		P		P	P	
	Fetal	P	P	P		P	P	P ⁵
	Abdominal ⁶	P	P	P		P	P	P ₂
	Intra-operative (Specify) ⁷	P	P	Р		P	Р	P ⁵
	Intra-operative (Neuro)	P		P		P	P	P2
	Laparoscopic							
	Pediatric	P	P	P		P	P	P ⁵
	Small Organ (Thyroid, Breast, Testes, etc.)	P	P	P		P	P	Ъ ₂
	Neonatal Cephalic	P	P	P		P	P	P5
T . 1 T	Adult Cephalic							
Fetal Imaging &	Trans-rectal							
Other	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non- Card.)							
	Musculo-skel. (Conventional)	Р	P	Р		P	P	P ^{5, 8}
	Musculo-skel. (Superficial)	P	P	P	-	Р	P	P ^{5, 8}
	Intravascular							
	Other (Specify) ⁸ (3D/4D)							
	Cardiac Adult	l						
	Cardiac Pediatric							
	Intravascular (Cardiac)							
Cardiac	Trans-esoph. (Cardiac)						<u> </u>	
	Intra-cardiac							
	Other (Specify)							<u> </u>
	Peripheral Vascular	P	P	P		P	P	P ⁸
Peripheral Vessel	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

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: ZS3 and z.one_{pro}Ultrasound Systems

Transducer: Linear Transducer L8-3

Indications for Use (Describe)

Clinical Applicatio	n (1)	Mode	of Operat	ion	有 學、漢	Paint Co.	en er er	66 46
General	Specific	В	М	PWD ²	CWD	Color	Combined	Other ^{5, 8}
(Track I Only)	(Tracks 1 & 3)		ļ <u>.</u>			Doppler ³	Modes ⁴	
Ophthalmic	Ophthalmic		 					P ⁵
	Fetal	P	P	P		P	P	
	Abdominal ⁶	P	P	P		P	Р	P ⁵
	Intra-operative (Specify) ⁷	P	P	P		Р	P	P ⁵
	Intra-operative (Neuro)	P		P		P	P	P ⁵
	Laparoscopic		1					
	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				-			
Fetal Imaging &	Trans-rectal			1				1
Other	Trans-vaginal	-			*			
	Trans-urethral		1					
	Trans-esoph. (non-							
	Musculo-skel. (Conventional)	Р	P	P		P	P	P ^{5, 8}
	Musculo-skel (Superficial)	Р	P	P		Р	P	P ^{5, 8}
	Intravascular							
	Other (Specify) ⁸ 3D/4D							
	Cardiac Adult							
	Cardiac Pediatric	1					l	
	Intravascular (Cardiac)							
Cardiac	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)	T						
	Peripheral Vascular	Р	P	P		P	P	P ⁵ P ⁸
Peripheral Vessel	Other (Specify) 3D/4D							

N = new indication; P=previously cleared by the FDA 510(k) K141641

⁸ Freehand tissue elasticity



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)

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.oneproUltrasound Systems Transducer: Linear Transducer L14-5sp

Indications for Use (Describe)

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

Clinical Applicatio	n. Television	Mode	of Operat	ion	Min Fig.	i i i i i i i i i i i i i i i i i i i	-403 K. 74	e da
General	Specific	В	М	PWD ²	CWD	Color	Combined	Other ^{5, 8}
(Track 1 Only)	(Track 1 & 3)			1		Doppler ³	Modes ⁴	
Ophthalmic	Ophthalmic	P		P		P	P	p5
	Fetal	P	P	P		P	P	1 *
	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					l		
	Pediatric	P	P	P		P	P	₽⁵
	Small Organ (Thyroid, Breast, Testes, etc.)	P	P	P		P	P	P ⁵
•	Neonatal Cephalic	P	P	P		P	P	P ⁵
	Adult Cephalic	i					1	T
Fetal Imaging &	Trans-rectal							
Other	Trans-vaginal		T T					
	Trans-urethral	İ						
	Trans-esoph. (non- Card.)							
	Musculo-skel. (Conventional)	Р	P	P		P	P	P ^{5, 8}
	Musculo-skel. (Superficial)	Р	P	Р		Р	P	P ^{5, 8}
	Întravascular							
	Other (Specify) ⁸ 3D/4D							
	Cardiac Adult							
	Cardiac Pediatric	·						
	Intravascular (Cardiac)		-					
Cardiac	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
	Peripheral Vascular	P	P	Р		Р	Р	P ⁵
Peripheral Vessel	Other (Specify) 3D/4D							

N = new indication; P=previously cleared by the FDA 510(k) K141641

Includes B-Mode and Harmonic (contrast) imaging (HI)

14 OF 21

² Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)

Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)

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)

⁸Freehand tissue elasticity

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 L14-5w

Indications for Use (Describe)

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

Clinical Application	r / Language / Langua	Mode	of Operat	ion				1/10/27 12:11
General	Specific	В	М	PWD ²	CWD	Color	Combined	Other ^{5, 8}
(Track 1 Only)	(Tracks 1 & 3)		177		0772	Doppler ³	Modes ⁴	
Ophthalmic	Ophthalmic	P		P		P	P	- 5
	Fetal	P	P	P		P	P	P ⁵
	Abdominal ⁶	P	P	P		P	P	P ⁵
	Intra-operative (Specify) ⁷	P	P	Р		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
n . 17 . 4	Adult Cephalic							
Fetal Imaging & Other	Trans-rectal						_	
Otner	Trans-yaginal							
	Trans-urethral							
,	Trans-esoph. (non- Card.)							
	Musculo-skel. (Conventional)	Р	P	Р		P	P	P ^{5, 8}
	Musculo-skel. (Superficial)	Р	P	Р		P	P	P ^{5, 8}
	Intravascular (Cardiac)							
	Other (Specify) ⁸ 3D/4D							
7	Cardiac Adult			1				
	Cardiac Pediatric							
	Intravascular (Cardiac)							
Cardiac	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
B : 1 177	Peripheral Vascular	P	P	P		P	P	P ⁵ P ⁸
Peripheral Vessel	Other (Specify) 3D/4D							

N = new indication; P=previously cleared by the FDA 510(k) K141641

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

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 L20-5

Indications for Use (Describe)

Clinical Applicatio	n	Mode	of Operat	ion	1020073-1910			
General (Track 1 Only)	Specific (Tracks 1 & 3)	В	M	PWD²	CWD	Color Doppler ³	Combined Modes ⁴	Other ^{5, 8}
Ophthalmic	Ophthalmic	P		P		P	P	
	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	[T					
	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
Fetal Imaging &	Adult Cephalic							
Other	Trans-rectal							<u> </u>
	Trans-vaginal							
	Trans-urethral						<u> </u>	
	Trans-esoph. (non-Card.)			I				
	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 Adult							
	Cardiac Pediatric							
a "	Intravascular (Cardiac)							
Cardiac	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
***	Peripheral Vascular	Р	P	Р		P	P	P ⁵
Peripheral Vessel	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

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.oneproUltrasound Systems

Transducer: Tran-Esophageal Transducer: P8-3TEE

Indications for Use (Describe)

Clinical Applicatio	n	Mode	of Operat	ion				
General (Track 1 Only)	Specific (Tracks 1 & 3)	В	М	PWD ²	CWD	Color Doppler ³	Combined Modes ⁴	Other ^{5, 8}
Ophthalmic	Ophthalmic							
	Fetal							
	Abdominal	T					<u> </u>	
	Intra-operative (Specify) ⁷							
	Intra-operative (Neuro)							ļ
	Laparoscopic		1					
	Pediatric							
	Small Organ (Thyroid, Breast, Testes, etc.)							
	Neonatal Cephalic							
T	Adult Cephalic							
Fetal Imaging & Other	Trans-rectal							
Other	Trans-vaginal							
	Trans-urethral		,	·				·
	Trans-esoph. (non- Card.)	P	P	P	P	P	P	P ⁵
	Musculo-skel.							
	(Conventional) Musculo-skel.	-		 		 		
	(Superficial)			<u> </u>		<u></u>		
	Intravascular							<u> </u>
	Other (Specify) (3D/4D)							
	Cardiac Adult							
	Cardiac Pediatric							
Condina	Intravascular (Cardiac)							1
Cardiac	Trans-esoph. (Cardiac)	P	P	P	P	P	P	P ⁵
	Intra-cardiac					<u> </u>		
	Other (Specify)							
D 14 137 1	Peripheral Vessel	l						ļ
Peripheral Vessel	Other (Specify)					<u> </u>		l

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)

⁸Freehand tissue elasticity

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: ZS3 and 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)

Clinical Application	n s	Mode	of Operat	ion	griga d	发通摄影(数)	stichten and a	公園/電池
General	Specific	В	l _M	PWD^2	CWD	Color	Combined	Other ^{5,8}
(Track 1 Only)	(Tracks 1 & 3)			1,112		Doppler ³	Modes ⁴	
Ophthalmic	Ophthalmic							
	Fetal	<u> </u>					<u> </u>	
	Abdominal		<u> </u>					
	Intra-operative (Specify) ⁷							
	Intra-operative (Neuro)	 	+					
	Laparoscopic	 	 		-			
	Pediatric		-			-		
				-				
	Small Organ (Thyroid,							
	Breast, Testes, etc.) Neonatal Cephalic		+	-			<u> </u>	
				 	 		*	
Fetal Imaging &	Adult Cephalic		+	1				
Other	Trans-rectal						 -	
	Trans-vaginal		-		-			
	Trans-urethral		 			-	 	
	Trans-esoph. (non-							
	Card.)		 				 	
	Musculo-skel.							
	(Conventional)	ļ						
	Musculo-skel.							
	(Superficial)			_				
	Intravascular							
	Other (Specify)							
	(3D/4D)		<u> </u>					
	Cardiac Adult	_					ļ	
	Cardiac Pediatric							
G . 1" -	Intravascular (Cardiac)		<u> </u>					
Cardiac	Trans-esoph. (Cardiac)							
	Intra-cardiac				<u> </u>			
	Other (Specify)	P	P	P	P	P	P	
	Peripheral vascular							
Peripheral Vessel	Other (Specify)		1					
	=nreviously cleared by FDA	510/le) I	7141641	St Juda KO2	1066 & K07	3700-	·	

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

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.oneproUltrasound 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 Applicatio	n	Mode	of Operat	ion				
General (Track 1 Only)	Specific (Tracks 1 & 3)	В	М	PWD ²	CWD	Color Doppler ³	Combined Modes ⁴	Other ^{5, 8}
Ophthalmic	Ophthalmic	Ì						
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-urethral Trans-esoph. (non-Card.) Musculo-skel. (Conventional) Musculo-skel. (Superficial) Intravascular Intra-luminal Other (Specify) (3D/4D) Cardiac Adult				P			
Cardiac	Cardiac Pediatric Intravascular (Cardiac) Trans-esoph. (Cardiac) Intra-cardiac Other (Intra-Cardiac)				P			
Peripheral Vessel	Peripheral vascular Other (Specify) =nreviously cleared by FDA							

N = new indication; P=previously cleared by FDA 510(k) K141641

¹ Includes B-Mode and Harmonic (contrast) imaging (HI)



FORM FDA 3881 (8/14)

² Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)

Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)

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

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: ZS3 and z.one_{pro}Ultrasound Systems

Transducer: A5CW (Common name Pencil Probe)

Indications for Use (Describe)

Clinical Application	n	Mode o	of Operat	ion				
General (Track 1 Only)	Specific (Tracks 1 & 3)	В	М	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-urethral Trans-soph, (non-Card.) Musculo-skel, (Conventional) Musculo-skel, (Superficial) Intravascular Other (Specify) (3D/4D)				P			
Cardiac	Cardiac Adult Cardiac Pediatric Intravascular (Cardiac) Trans-esoph. (Cardiac) Intra-cardiac Other (Intra-Cardiac)							
Peripheral Vessel	Peripheral vascular Other (Specify)				P			

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

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 C9-3sp

Indications for Use (Describe)

Clinical Application	raign) — Pri Silver Sil	Mode	of Operat	ion 💮 🔻		表情感感	1. 不測能2. (P1.5) /	的 情 豪格
General (Track I Only)	Specific (Track I & III)	В	М	PWD ²	CWD	Color Doppler ³	Combined Modes ⁴	Other ^{5, 8}
Ophthalmic	Ophthalmic							5
	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	TV.		1				
	Adult Cephalic			 		-		
General application	Trans-rectal		+	1				
application	Trans-vaginal	<u> </u>		1				
	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					ļ		ļ
	Other (Specify) (3D/4D)		:					
	Cardiac Adult					ļ		ļ
	Cardiac Pediatric							ļ
O1:	Intravascular (Cardiac)					<u> </u>		
Cardiac	Trans-esoph. (Cardiac)							ļ
	Intra-cardiac							<u> </u>
	Other (Specify)							1.3
D 1 1 1	Peripheral vascular	N	N	N		N	N	N ⁵
Peripheral vascular	Other (Specify)					<u> </u>		

N = new indication; P=previously cleared by FDA 510(k) K141641



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



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 Sy	ystems, Inc.						
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	Mountain View, CA	94043						
Contact Person:	Steve Geerdes							
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Date Prepared:	Revised May 14, 201							
Trade Name(s):	ZS3 Ultrasound Syste	ZS3 Ultrasound System						
	z.one _{pro} Ultrasound S	z.one _{pro} Ultrasound System						
Common Name:	Diagnostic Ultrasoun	d System with Accessories						
Classification:	II							
Classification	Ultrasonic Pulsed	Ultrasonic Pulsed	Diagnostic Ultrasound					
Name(s):	Doppler Imaging	Echo Imaging System	Transducer					
	System							
Regulation	21 CFR 892.1550	892.1560	892.1570					
Number:								
Product Code:	IYN	IYO	ITX					
Classification	Radiology							
Panel:								
Predicate Devices:	ZONARE's ZS3 Ultra	asound System	K150249					
	7							

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 Ultrasound platform
	ZS3 and z.one _{pro} Ultrasound Systems (ZONARE Medical Systems)	(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

Item	ZS3 Ultrasound Platform	ZS3 Ultrasound platform
	ZS3 and z.one pro Ultrasound Systems (ZONARE Medical Systems)	(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	Same
	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	
Principle of	Applying high voltage burst to the Piezoelectric material in the	Same
Operation	transducer and detect reflected echo to construct the diagnostic	
	image	~
Acoustic Output	Track 3:MI, TIS, TIC, TIB (TI Range 0-6.0)	Same
	Derated I _{SPTA} : 720mW/cm ² maximum,	
	Mechanical Index ≤ 1.9 maximum or Derated I _{SPPA} ≤ 190	
	W/cm ² max	
	Ophthalmic use:	
	$TI = Max (TIS_as, TIC) \le 1;$	
T 1 T	ISPTA.3 \leq 50mW/cm2; and MI \leq 0.23	0
Transducer Types	Linear Array	Same
	Curved Linear Array	
	Phased Array	
	Trans-esophageal Pencil Probe	
	Intracavitary	
Transducer	1.0 – 20.0 MHz	Same
Frequency	1.0 – 20.0 MHZ	Same
rrequency		
DICOM	Yes	Same
Compliant		
Special	Yes	Same
Procedures User		
Interface		
Display Monitor/	ZS3: Color 19" Liquid Crystal Display (LCD)/ 2 arm	Same
Monitor Arm	articulation plus tilt and swivel	
	z.one pro: Color 17" Liquid Crystal Display (LCD)/ Tilt and	
	swivel	
Scanner	Integrated	Same
Transducer	Multi-Transducer Port (Three)	Same
Port(s)	Height man (in an autismal ma) 157.5 am ((2in)	Como
Dimensions/	Height, max (in operational use) 157.5cm (62in)	Same
Weight	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)	
	Weight, 03.3kg (17710)	
Power	100-240V options, ~ 50-60Hz, 6A max	Same
Requirements	, , , , , , , , , , , , , , , , , , , ,	-
Rechargeable	Yes (up to 3.0 hour operation per charge)	Same
Battery	1 1 2 3 37	-
Wireless	Yes (IEEE 802.11b/g, Wi-Fi compliant)	Same

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Item	ZS3 Ultrasound Platform	ZS3 Ultrasound platform	
	ZS3 and z.one pro Ultrasound Systems	(ZONARE Medical Systems)	
	(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	PASS
	performance specifications	
Electrical Safety	In accordance with IEC 60601-1	PASS
EMC Testing	In accordance with IEC 60601-	PASS
	1-2	
Thermal and Acoustic Output	In accordance with IEC 60601-	PASS
	2-37	
Biocompatibility	In accordance with ISO 10993	PASS
Cleaning & Disinfection	In accordance with FDA	PASS
	Guidance Document	
Software Validation &	In accordance with 62304 and	PASS
Verification	FDA Guidance Document	
	Principles of Software	
	Validation	

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.