

## 510(k) Summary of Safety & Effectiveness

Prepared in accordance with 21 CFR Part 807.92(c)

The assigned 510(k) number is: K101091

### Applicant Information:

JUN 25 2010

**Date Prepared:** June 14, 2010

**Name:** ZONARE Medical Systems, Inc.  
420 North Bernardo Avenue  
Mountain View, CA 94043

**Contact Persons:** Linda J. Moore  
Director, Regulatory Affairs & Quality Assurance

**Telephone Numbers:** 650-230-2724

**Fax Number:** 650-967-9036

**Email:** [lmoore@zonare.com](mailto:lmoore@zonare.com)

### Device Information:

**Trade Name:** ZONARE z.one *Ultra* Ultrasound System

**Device Name:** ZONARE Diagnostic Ultrasound System

	FR Number	Product Code
Ultrasonic Pulsed Doppler Imaging System	892.1550	90-IYN
Ultrasonic Pulsed Echo Imaging System	892.1560	90-IYO
Diagnostic Ultrasound Transducer	892.1570	90-ITX

**Marketed Device(s):** The ZONARE z.one *Ultra* Ultrasound System (K022858), (K082326), EPMed Systems (St. Jude, K031066) (K073709), Philips HD11 (K062247), and Sonosite, Inc. (K053069) devices currently in commercial distribution.

**Device Description:** The z.one *Ultra* is a general purpose diagnostic ultrasound system which consists of a combination of portable scanner(s) less than 10 inches wide and 3 inches high, embedded in the cart, or that can be held by the user in one hand. They include buttons for controlling the system and may have a screen that display ultrasound images and user interface or be without the screen (monitor) and user interface. The portable scanner can be held by the user in one hand and accommodates a removable transducer module. Signals received from the transducer module are digitized and preprocessed. The transducer module comes into contact with the patient and both transmit and receive ultrasound energy.

The docking station (aka carts) provides holders for the portable scanner, and transducer modules, as well as battery chargers and other accessories. The modification for this submission includes new indication for use and off the shelf transducers.

**Indications for 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); Musculoskeletal (conventional & superficial); 3D/4D; Cardiac – Adult/Pediatric/Fetal; Intra-Cardiac; Pelvic; Peripheral vascular; harmonic tissue and contrast imaging and Tissue elasticity.

**Comparison with Predicate Device:** With respect to features and applications, the ZONARE z.one Ultra with the new ophthalmic indication for use and the off the shelf intra-cardiac echo catheter (View-Flex) is comparable and substantially equivalent to the currently marketed ZONARE z.one and the predicate devices listed in predicate devices section in terms of portability, features and functionality. Additionally, they have the same important safety and effectiveness features, as well as design, materials, and construction.

**Non-clinical tests:** The device has been evaluated according to the applicable medical device quality systems, safety standards for acoustic output, biocompatibility, verification and validation, cleaning, and disinfection effectiveness as well as for thermal, electrical, and mechanical safety, those applicable to ZONARE’s ultrasound product are:

ISO 14971	Medical Devices – applications of risk management to medical devices
IEC/UL 60601-1	Medical Electrical Equipment (MEE) – General Requirements for Safety
IEC 60601-1-1	Medical Electrical Equipment for Systems
IEC 60601-1-2	EMC
IEC 60601-1-4	MEE – Programmable electrical medical systems
IEC 60601-2-37	Safety of ultrasonic medical diagnostic and monitoring equipment
IEC 62304	Medical Device software – software life cycle processes
ISO 10993	Biological evaluation of medical devices
AIUM	Medical Ultrasound Safety, American Institute of Ultrasound in Medicine (2002)

**Clinical Tests:** Non Required

**Conclusion:** The device conforms to applicable medical device safety standards and compliance for safety and effectiveness is verified through defined evaluation and market surveillance. The ZONARE z.one Ultra Diagnostic Ultrasound System is substantially equivalent with respect to safety and effectiveness to devices current cleared for market.



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

**JUN 25 2010**

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

Re: K101091  
Trade/Device Name: The z.one Ultra Ultrasound System  
Regulation Number: 21 CFR 892.1550  
Regulation Name: Ultrasonic pulsed doppler imaging system  
Regulatory Class: II  
Product Code: IYN, IYO, and ITX  
Dated: June 9, 2010  
Received: June 10, 2010

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we 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). 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.

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

Transducer Model Number

- Curvilinear Transducer C4-1
- Curvilinear Transducer C5-2
- Curvilinear Transducer C6-2
- Curvilinear Transducer C9-3
- Curvilinear Transducer C8-3 (3D/4D)
- Curvilinear Transducer C9-4t
- Phase (Sector) Array Transducer P4-1
- Phase (Sector) Array Transducer P4-1c
- Phased (Sector) Array Transducer P10-4
- Endo-Cavity Transducer E9-4
- Endo-Cavity Transducer E9-4 (3D)
- Linear Transducer L10-5

Linear Transducer L8-3  
Linear Transducer L12-4v  
Linear Transducer L14-5sp  
Linear Transducer L14-5w  
Tran-Esophageal Transducer P8-3T  
St. Jude EP ViewFlex PLUS ICE Catheter model # VF-PM Part #09-2005  
A2CW (Common name Pencil Probe)  
A5CW (Common name Pencil Probe)

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

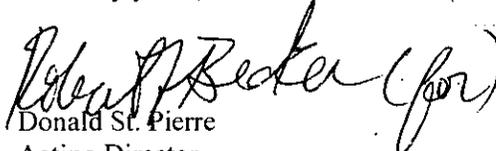
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); 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.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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.

If you have any questions regarding the content of this letter, please contact Shahram Vaezy at (301) 796-6242.

Sincerely yours,



Donald St. Pierre  
Acting Director  
Division of Radiological Devices  
Office of *In Vitro* Diagnostic Device  
Evaluation and Safety  
Center for Devices and Radiological Health

Enclosure(s)



## Indications for Use Statement

510(K) Number (if known): K101091

Device Name: The z.one Ultra Ultrasound system

**Indications for 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); Musculoskeletal (conventional & superficial); 3D/4D; Cardiac – Adult/Pediatric/Fetal; Intra-Cardiac; Pelvic; Peripheral vascular; harmonic tissue and contrast imaging and Tissue elasticity.

Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Robert J. Beckel  
Division Sign-Off  
Office of In Vitro Diagnostic Devices  
Evaluation and Safety

510(K) K101091

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### 1.3 Diagnostic Ultrasound Indications for use

510(K) Number (if known): \_\_\_\_\_

System Name: ZONARE zone Ultra Ultrasound Diagnostic System

Device Name: Union of all Transducer Types

Indications for Use: This device is intended for use by a qualified physician for ultrasound evaluation of the following: Fetal, Abdominal, Intraoperative, Pediatric, Ophthalmic, Intra-cardiac, Small organ/parts (breast/testes, thyroid, etc), Transvaginal, Transrectal, Transcranial, Trans-esoph, Trans-urethral, OB/GYN, Cardiac, Pelvic, Neonatal/Adult cephalic. Vascular, 3D/4D, Tissue elasticity, Musculoskeletal, cardiac, Superficial Musculoskeletal, and Peripheral Vascular applications and others as shown below.

Clinical Application		Mode of Operation							
General	Specific	B	M	PWD <sup>2</sup>	CWD CWD Aux	Color Doppler <sup>3</sup>	Combined Modes <sup>4</sup>	Other <sup>5,6</sup>	
Ophthalmic	Ophthalmic	N		N		N	N		
General Application	Fetal	P	P	P	P	P	P	P <sup>5</sup>	
	Abdominal	P	P	P	P	P	P	P <sup>5</sup>	
	Intra-operative (Specify) <sup>6</sup>	P	P	P		P	P	P <sup>5</sup>	
	Intra-operative (Neuro)	P		P		P	P	P <sup>5</sup>	
	Laparoscopic								
	Pediatric	P	P	P	P	P	P	P <sup>5</sup>	
	Pediatric Aux				P				
	Small Organ (Thyroid, Breast, Testes, etc.)	P	P	P		P	P	P <sup>5</sup> P <sup>8</sup>	
	Neonatal Cephalic	P	P	P	P	P	P	P <sup>5</sup>	
	Adult Cephalic	P	P	P	P	P	P	P <sup>5</sup>	
	Trans-rectal	P	P	P		P	P	P <sup>5</sup>	
	Trans-vaginal	P	P	P		P	P	P <sup>5</sup>	
	Trans-urethral								
	Trans-esoph. (non- Card.)	P	P	P	P	P	P	P <sup>5</sup>	
	Musculo-skel. (Conventional)	P	P	P			P	P	P <sup>5,8</sup>
	Musculo-skel. (Superficial)	P	P	P			P	P	P <sup>5,8</sup>
	Intra-luminal								
Other (Specify) (3D/4D)	P	P	P			P	P		
Cardiac	Cardiac Adult	P <sup>1</sup>	P	P	P	P	P	P <sup>5</sup>	
	Cardiac Adult Aux				P				
	Cardiac Pediatric	P	P	P	P	P	P	P <sup>5</sup>	
	Cardiac Pediatric Aux				P				
	Trans-esoph. (Cardiac)	P	P	P	P	P	P	P <sup>5</sup>	
	Other (Specify) (3D/4D)	P	P	P	P	P	P		
Peripheral vascular	Other (Intra-Cardiac)*	P	P	P		P			
	Peripheral Vessel	P	P	P	P	P	P	P <sup>5</sup> P <sup>8</sup>	
	Peripheral Vessel Aux				P				
	Other (Specify) (3D/4D)	P	P	P		P	P		

N = new indication; P = previously cleared by FDA 510(k) K022858 & K082326, \*ST. Jude # 073709 E=Added under Appendix E

<sup>1</sup> Includes B-Mode and Harmonic (contrast) imaging (HI)

<sup>2</sup> Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)

<sup>3</sup> Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)

<sup>4</sup> Includes B+M, B+M+CM, M+CM, B+CD+M+CM, B+CD+PWD where CD could represent (CD, DPD, PD, or BD)

<sup>5</sup> Color M-Mode (CM)

<sup>6</sup> Abdominal includes renal, GYN/Pelvic

<sup>7</sup> Intra operative include abdominal, thoracic (cardiac) and vascular (PV)

<sup>8</sup> Freehand tissue elasticity

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 Division Sign-Off  
 Office of In Vitro Diagnostic Devices  
 Evaluation and Safety  
 510(K) K101091

510(K) Number (if known): \_\_\_\_\_

System Name: ZONARE z.one Ultra Ultrasound Diagnostic System

Device Name: Curvilinear Transducer C4-1

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

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Track I & III)	B	M	PWD <sup>2</sup>	CWD	Color Doppler <sup>3</sup>	Combined Modes <sup>4</sup>	Other <sup>5</sup>
Ophthalmic	Ophthalmic							
	Fetal	E	E	E		E	E	
	Abdominal	E	E	E		E	E	
	Intra-operative (Specify) <sup>7</sup>							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	E	E	E		E	E	
	Small Organ (Thyroid, Breast, Testes, etc.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Conventional)	E	E	E		E		
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other (Specify) (3D/4D) contrast	E	E	E		E	E	
Cardiac	Cardiac Adult	E <sup>1</sup>	E	E		E	E	
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral vascular	Peripheral vascular							
	Other (Specify)							

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

<sup>1</sup> Includes B-Mode and Harmonic (contrast) imaging (HI)

<sup>2</sup> Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)

<sup>3</sup> Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)

<sup>4</sup> Includes B+M, B+M+CM, M+CM, B+CD+M+CM, B+CD+PWD where CD could represent (CD, DPD, PD, or BD)

<sup>5</sup> Color M-Mode (CM)

<sup>6</sup> Abdominal includes renal, GYN/Pelvic

<sup>7</sup> Intra operative include abdominal, thoracic (cardiac) and vascular (PV)

<sup>8</sup> Freehand tissue elasticity

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*[Signature]*

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510(K) K101091

510(K) Number (if known): \_\_\_\_\_

System Name: ZONARE z.one Ultra Ultrasound Diagnostic System

Device Name: Curvilinear Transducer C5-2

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

Clinical Application		Mode of Operation						
General	Specific (Track I & III)	B	M	PWD <sup>2</sup>	CWD	Color Doppler <sup>3</sup>	Combined Modes <sup>4</sup>	Other <sup>5</sup>
Ophthalmic	Ophthalmic							
General applications	Fetal	P	P	P		P	P	P <sup>5</sup>
	Abdominal <sup>6</sup>	P	P	P		P	P	P <sup>5</sup>
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	P	P	P		P	P	P <sup>5</sup>
	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)							
	Intra-luminal							
	Other (Specify) (3D/4D)							
	Cardiac	Cardiac Adult						
Cardiac Pediatric								
Trans-esoph. (Cardiac)								
Other (Specify)								
Peripheral Vascular	Peripheral Vascular	P	P	P		P	P	P <sup>5</sup>
	Other (Specify)							

N = new indication; P=previously cleared by FDA 510(k) K022858 & K082326, E=Added under Appendix E

<sup>1</sup> Includes B-Mode and Harmonic (contrast) imaging (HI)

<sup>2</sup> Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)

<sup>3</sup> Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)

<sup>4</sup> Includes B+M, B+M+CM, M+CM, B+CD+M+CM, B+CD+PWD where CD could represent (CD, DPD, PD, or BD)

<sup>5</sup> Color M-Mode (CM)

<sup>6</sup> Abdominal includes renal, GYN/Pelvic

<sup>7</sup> Intra operative include abdominal, thoracic (cardiac) and vascular (PV)

<sup>8</sup> Freehand tissue elasticity

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510(K) K101091

510(K) Number (if known): \_\_\_\_\_

System Name: ZONARE z.one Ultra Ultrasound Diagnostic System

Device Name: Curvilinear Transducer C6-2

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

Clinical Application		Mode of Operation						
General	Specific (Track I & III)	B	M	PWD <sup>2</sup>	CWD	Color Doppler <sup>3</sup>	Combined Modes <sup>4</sup>	Other <sup>5, 8</sup>
Ophthalmic	Ophthalmic							
General applications	Fetal	P	P	P		P	P	P <sup>5</sup>
	Abdominal <sup>6</sup>	P	P	P		P	P	P <sup>5</sup>
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	P	P	P		P	P	P <sup>5</sup>
	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)							
	Intra-luminal							
Other (Specify) (3D/4D)								
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vascular	Peripheral Vascular	P	P	P		P	P	P <sup>5</sup>
	Other (Specify)							

N = new indication; P=previously cleared by FDA 510(k) K022858 & K082326, E=Added under Appendix E

<sup>1</sup> Includes B-Mode and Harmonic (contrast) imaging (HI)

<sup>2</sup> Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)

<sup>3</sup> Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)

<sup>4</sup> Includes B+M, B+M+CM, M+CM, B+CD+M+CM, B+CD+PWD where CD could represent (CD, DPD, PD, or BD)

<sup>5</sup> Color M-Mode (CM)

<sup>6</sup> Abdominal includes renal, GYN/Pelvic

<sup>7</sup> Intra operative include abdominal, thoracic (cardiac) and vascular (PV)

<sup>8</sup> Freehand tissue elasticity

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Evaluation and Safety

510(K) K101091

510(K) Number (if known): \_\_\_\_\_

System Name: ZONARE z.one Ultra Ultrasound Diagnostic System

Device Name: Curvilinear Transducer C9-3

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

Clinical Application		Mode of Operation							
General	Specific (Track I & III)	B	M	PWD <sup>2</sup>	CWD	Color Doppler <sup>3</sup>	Combined Modes <sup>4</sup>	Other <sup>5</sup>	
Ophthalmic	Ophthalmic								
General applications	Fetal	P	P	P		P	P	P <sup>5</sup>	
	Abdominal <sup>6</sup>	P	P	P		P	P	P <sup>5</sup>	
	Intra-operative (Abdominal)	P	P	P	P	P	P	P <sup>5</sup>	
	Intra-operative (Vascular)	P	P	P	P	P	P	P <sup>5</sup>	
	Laparoscopic								
	Pediatric	P	P	P		P	P	P <sup>5</sup>	
	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	P	P <sup>5</sup>
	Musculo-skel. (Superficial)	P	P	P	P	P	P	P	P <sup>5</sup>
	Intra-luminal								
	Other (Specify) (3D/4D)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Trans-esoph. (Cardiac)								
	Other (Specify)								
Peripheral Vascular	Peripheral Vascular	P	P	P		P	P	P <sup>5</sup>	
	Other (Specify)								

N = new indication; P=previously cleared by FDA 510(k) K082326, E=Added under Appendix E

<sup>1</sup> Includes B-Mode and Harmonic (contrast) imaging (HI)

<sup>2</sup> Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)

<sup>3</sup> Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)

<sup>4</sup> Includes B+M, B+M+CM, M+CM, B+CD+M+CM, B+CD+PWD where CD could represent (CD, DPD, PD, or BD)

<sup>5</sup> Color M-Mode (CM)

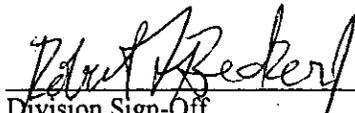
<sup>6</sup> Abdominal includes renal, GYN/Pelvic

<sup>7</sup> Intra operative include abdominal, thoracic (cardiac) and vascular (PV)

<sup>8</sup> Freehand tissue elasticity

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 Evaluation and Safety

510(K) K101091

510(K) Number (if known): \_\_\_\_\_

System Name: ZONARE z.one Ultra Ultrasound Diagnostic System

Device Name: Curvilinear Transducer C8-3 (3D/4D)

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

Clinical Application		Mode of Operation						
General	Specific (Track I & III)	B	M	PWD <sup>2</sup>	CWD	Color Doppler <sup>3</sup>	Combined Modes <sup>4</sup>	Other <sup>5, 8</sup>
Ophthalmic	Ophthalmic							
General applications	Fetal	P	P	P		P	P	P <sup>5</sup>
	Abdominal <sup>6</sup>	P	P	P		P	P	P <sup>5</sup>
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	P	P	P		P	P	P <sup>5</sup>
	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)							
	Intra-luminal							
Other (Specify) (3D/4D)	P	P	P			P	P	P <sup>5</sup>
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vascular	Peripheral Vascular	P	P	P		P	P	P <sup>5</sup>
	Other (Specify)							

N = new indication; P=previously cleared by FDA 510(k) K082326, E=Added under Appendix E

<sup>1</sup> Includes B-Mode and Harmonic (contrast) imaging (HI)

<sup>2</sup> Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)

<sup>3</sup> Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)

<sup>4</sup> Includes B+M, B+M+CM, M+CM, B+CD+M+CM, B+CD+PWD where CD could represent (CD, DPD, PD, or BD)

<sup>5</sup> Color M-Mode (CM)

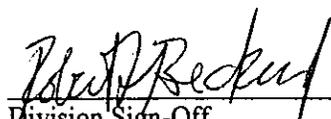
<sup>6</sup> Abdominal includes renal, GYN/Pelvic

<sup>7</sup> Intra operative include abdominal, thoracic (cardiac) and vascular (PV)

<sup>8</sup> Freehand tissue elasticity

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

  
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510(K) K101091

510(K) Number (if known): \_\_\_\_\_

System Name: ZONARE z.one Ultra Ultrasound Diagnostic System

Device Name: Curvilinear Transducer C9-4t

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

Clinical Application		Mode of Operation							
General (Track I Only)	Specific (Track I & III)	B	M	PWD <sup>2</sup>	CWD	Color Doppler <sup>3</sup>	Combined Modes <sup>4</sup>	Other <sup>5, 8</sup>	
General application	Ophthalmic								
	Fetal								
	Abdominal	E	E	E		E	E		
	Intra-operative (Specify) <sup>7</sup>								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	E	E	E		E	E		
	Small Organ (Thyroid, Breast, Testes, etc.)								
	Neonatal Cephalic	E	E	E		E	E		
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skel. (Conventional)	E	E	E		E	E		
	Musculo-skel. (Superficial)	E	E	E		E	E		
	Intra-luminal								
	Other (Specify) (3D/4D) Vet abdominal	E	E	E		E	E		
	Cardiac	Cardiac Adult							
		Cardiac Pediatric	E	E	E		E	E	
Trans-esoph. (Cardiac)									
Other (Specify) vet cardiac		E	E	E		E	E		
Peripheral vascular	Peripheral vascular								
	Other (Specify)								

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

<sup>1</sup> Includes B-Mode and Harmonic (contrast) imaging (HI)

<sup>2</sup> Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)

<sup>3</sup> Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)

<sup>4</sup> Includes B+M, B+M+CM, M+CM, B+CD+M+CM, B+CD+PWD where CD could represent (CD, DPD, PD, or BD)

<sup>5</sup> Color M-Mode (CM)

<sup>6</sup> Abdominal includes renal, GYN/Pelvic

<sup>7</sup> Intra operative include abdominal, thoracic (cardiac) and vascular (PV)

<sup>8</sup> Freehand tissue elasticity

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510(K) K101091

510(K) Number (if known): \_\_\_\_\_

System Name: ZONARE z.one Ultra Ultrasound Diagnostic System

Device Name: Phase (Sector) Array Transducer P4-1

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

Clinical Application		Mode of Operation						
General	Specific (Track I & III)	B	M	PWD <sup>2</sup>	CWD	Color Doppler <sup>3</sup>	Combined Modes <sup>4</sup>	Other <sup>5</sup>
Ophthalmic	Ophthalmic							
General application	Fetal	P	P	P	P	P	P	P <sup>5</sup>
	Abdominal <sup>6</sup>	P	P	P	P	P	P	P <sup>5</sup>
	Intra-operative (Specify) <sup>7</sup>							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	P	P	P	P	P	P	P <sup>5</sup>
	Small Organ (Thyroid, Breast, Testes, etc.)							
	Neonatal Cephalic	P	P	P	P	P	P	P <sup>5</sup>
	Adult Cephalic/ transcranial	P	P	P	P	P	P	P <sup>5</sup>
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult	P	P	P	P	P	P	P <sup>5</sup>
	Cardiac Pediatric	P	P	P	P	P	P	P <sup>5</sup>
	Trans-esoph. (Cardiac)							
	Other (Specify) (3D/4D)							
Peripheral vascular	Peripheral Vascular	P	P	P	P	P	P	P <sup>5</sup>
	Other (Specify)							

N = new indication; P=previously cleared by the FDA 510(k) K082326, E=Added under Appendix E

<sup>1</sup> Includes B-Mode and Harmonic (contrast) imaging (HI)

<sup>2</sup> Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)

<sup>3</sup> Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)

<sup>4</sup> Includes B+M, B+M+CM, M+CM, B+CD+M+CM, B+CD+PWD where CD could represent (CD, DPD, PD, or BD)

<sup>5</sup> Color M-Mode (CM)

<sup>6</sup> Abdominal includes renal, GYN/Pelvic

<sup>7</sup> Intra operative include abdominal, thoracic (cardiac) and vascular (PV)

<sup>8</sup> Freehand tissue elasticity

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510(K) K101091

510(K) Number (if known): \_\_\_\_\_

System Name: ZONARE z.one Ultra Ultrasound Diagnostic System

Device Name: Phase (Sector) Array Transducer P4-1c

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

Clinical Application		Mode of Operation						
General	Specific (Track I & III)	B	M	PWD <sup>2</sup>	CWD	Color Doppler <sup>3</sup>	Combined Modes <sup>4</sup>	Other <sup>5</sup>
Ophthalmic	Ophthalmic							
General application	Fetal	P	P	P	P	P	P	P <sup>5</sup>
	Abdominal <sup>6</sup>	P	P	P	P	P	P	P <sup>5</sup>
	Intra-operative (Specify) <sup>7</sup>							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	P	P	P	P	P	P	P <sup>5</sup>
	Small Organ (Thyroid, Breast, Testes, etc.)							
	Neonatal Cephalic	P	P	P	P	P	P	P <sup>5</sup>
	Adult Cephalic/ trans cranial	P	P	P	P	P	P	P <sup>5</sup>
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult	P <sup>1</sup>	P	P	P	P	P	P <sup>5</sup>
	Cardiac Pediatric	P	P	P	P	P	P	P <sup>5</sup>
	Trans-esoph. (Cardiac)							
	Other (Specify) (3D/4D)contrast	E	E	E		E	E	E <sup>5</sup>
Peripheral vascular	Peripheral Vascular	P	P	P	P	P	P	P <sup>5</sup>
	Other (Specify)							

N = new indication; P=previously cleared by the FDA 510(k) K082326, E=Added under Appendix E

<sup>1</sup> Includes B-Mode and Harmonic (contrast) imaging (HI)

<sup>2</sup> Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)

<sup>3</sup> Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)

<sup>4</sup> Includes B+M, B+M+CM, M+CM, B+CD+M+CM, B+CD+PWD where CD could represent (CD, DPD, PD, or BD)

<sup>5</sup> Color M-Mode (CM)

<sup>6</sup> Abdominal includes renal, GYN/Pelvic

<sup>7</sup> Intra operative include abdominal, thoracic (cardiac) and vascular (PV)

<sup>8</sup> Freehand tissue elasticity

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510(K) K101091

510(K) Number (if known): \_\_\_\_\_

System Name: ZONARE z.one Ultra Ultrasound Diagnostic System

Device Name: Phased (Sector) Array Transducer P10-4

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

Clinical Application		Mode of Operation						
General	Specific (Track I & III)	B	M	PWD <sup>2</sup>	CWD	Color Doppler <sup>3</sup>	Combined Modes <sup>4</sup>	Other <sup>5</sup>
Ophthalmic	Ophthalmic							
General application	Fetal	P	P	P	P	P	P	P <sup>5</sup>
	Abdominal <sup>6</sup>	P	P	P	P	P	P	P <sup>5</sup>
	Intra-operative (Specify) <sup>7</sup>	P	P	P		P	P	P <sup>5</sup>
	Intra-operative (Peuro)	P	P	P		P	P	P <sup>5</sup>
	Laparoscopic							
	Pediatric	P	P	P	P	P	P	P <sup>5</sup>
	Small Organ (Thyroid, Breast, Testes, etc.)							
	Neonatal Cephalic	P	P	P	P	P	P	P <sup>5</sup>
	Adult Cephalic/ trans cranial	P	P	P	P	P	P	P <sup>5</sup>
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other (Specify)							
	Cardiac	Cardiac Adult	P	P	P	P	P	P
Cardiac Pediatric		P	P	P	P	P	P	P <sup>5</sup>
Trans-esoph. (Cardiac)								
Other (Specify) (3D/4D)								
Peripheral vascular	Peripheral Vascular	P	P	P	P	P	P	P <sup>5</sup>
	Other (Specify)							

N = new indication; P=previously cleared by the FDA 510(k) K082326, E=Added under Appendix E

<sup>1</sup> Includes B-Mode and Harmonic (contrast) imaging (HI)

<sup>2</sup> Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)

<sup>3</sup> Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)

<sup>4</sup> Includes B+M, B+M+CM, M+CM, B+CD+M+CM, B+CD+PWD where CD could represent (CD, DPD, PD, or BD)

<sup>5</sup> Color M-Mode (CM)

<sup>6</sup> Abdominal includes renal, GYN/Pelvic

<sup>7</sup> Intra operative include abdominal, thoracic (cardiac) and vascular (PV)

<sup>8</sup> Freehand tissue elasticity

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*Robert J. Beckus*

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Evaluation and Safety

510(K) K101091

510(K) Number (if known): \_\_\_\_\_

System Name: ZONARE z.one Ultra Ultrasound Diagnostic System

Device Name: Endo-Cavity Transducer E9-4

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

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Track I & III)	B	M	PWD <sup>2</sup>	CWD	Color Doppler <sup>3</sup>	Combined Modes <sup>4</sup>	Other <sup>5, 8</sup>
Ophthalmic	Ophthalmic							
General application	Fetal	P	P	P		P	P	P <sup>5</sup>
	Abdominal							
	Intra-operative (Specify) <sup>7</sup>							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Thyroid, Breast, Testes, etc.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	P	P	P		P	P	P <sup>5</sup>
	Trans-vaginal	P	P	P		P	P	P <sup>5</sup>
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other (Specify) (3D/4D)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral vascular	Peripheral vascular							
	Other (Specify)							

N = new indication; P=previously cleared by FDA 510(k) K022858 & K082326, E=Added under Appendix E

<sup>1</sup> Includes B-Mode and Harmonic (contrast) imaging (HI)

<sup>2</sup> Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)

<sup>3</sup> Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)

<sup>4</sup> Includes B+M, B+M+CM, M+CM, B+CD+M+CM, B+CD+PWD where CD could represent (CD, DPD, PD, or BD)

<sup>5</sup> Color M-Mode (CM)

<sup>6</sup> Abdominal includes renal, GYN/Pelvic

<sup>7</sup> Intra operative include abdominal, thoracic (cardiac) and vascular (PV)

<sup>8</sup> Freehand tissue elasticity

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510(K) K101091

510(K) Number (if known): \_\_\_\_\_

System Name: **ZONARE z.one Ultra Ultrasound Diagnostic System**

Device Name: **Endo-Cavity Transducer E9-4 (3D)**

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

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Track I & III)	B	M	PWD <sup>2</sup>	CWD	Color Doppler <sup>3</sup>	Combined Modes <sup>4</sup>	Other <sup>5</sup>
Ophthalmic	Ophthalmic							
General application	Fetal	P	P	P		P	P	P <sup>5</sup>
	Abdominal							
	Intra-operative (Specify) <sup>7</sup>							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Thyroid, Breast, Testes, etc.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	P	P	P		P	P	P <sup>5</sup>
	Trans-vaginal	P	P	P		P	P	P <sup>5</sup>
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
Other (Specify) (3D/4D)	P	P	P		P	P	P <sup>5</sup>	
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral vascular	Peripheral vascular							
	Other (Specify)							

N = new indication; P=previously cleared by FDA 510(k) K082326, E=Added under Appendix E

<sup>1</sup> Includes B-Mode and Harmonic (contrast) imaging (HI)

<sup>2</sup> Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)

<sup>3</sup> Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)

<sup>4</sup> Includes B+M, B+M+CM, M+CM, B+CD+M+CM, B+CD+P+M+CM where CD could represent (CD, DPD, PD, or BD)

<sup>5</sup> Color M-Mode (CM)

<sup>6</sup> Abdominal includes renal, GYN/Pelvic

<sup>7</sup> Intra operative include abdominal, thoracic (cardiac) and vascular (PV)

<sup>8</sup> Freehand tissue elasticity

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510(K) 5101091

510(K) Number (if known): \_\_\_\_\_

System Name: ZONARE z.one Ultra Ultrasound Diagnostic System

Device Name: Linear Transducer L10-5

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

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Track I & III)	B	M	PWD <sup>2</sup>	CWD	Color Doppler <sup>3</sup>	Combined Modes <sup>4</sup>	Other <sup>5</sup>
General application	Ophthalmic	N		N		N	N	
	Fetal	P	P	P		P	P	P <sup>5</sup>
	Abdominal <sup>6</sup>	P	P	P		P	P	P <sup>5</sup>
	Intra-operative (Specify) <sup>7</sup>	P	P	P		P	P	P <sup>5</sup>
	Intra-operative (Neuro)	P		P		P	P	P <sup>5</sup>
	Laparoscopic							
	Pediatric	P	P	P		P	P	P <sup>5</sup>
	Small Organ (Thyroid, Breast, Testes, etc.)	P	P	P		P	P	P <sup>5</sup> P <sup>8</sup>
	Neonatal Cephalic	P	P	P		P	P	P <sup>5</sup>
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Conventional)	P	P	P		P	P	P <sup>5,8</sup>
	Musculo-skel. (Superficial)	P	P	P		P	P	P <sup>5,8</sup>
	Intra-luminal							
	Other (Specify) <sup>8</sup> (3D/4D)							
	Cardiac	Cardiac Adult						
Cardiac Pediatric								
Trans-esoph. (Cardiac)								
Other (Specify)								
Peripheral Vascular	Peripheral Vascular	P	P	P		P	P	P <sup>5</sup> P <sup>8</sup>
	Other (Specify) 3D/4D							

N = new indication; P=previously cleared by the FDA 510(k) K022858 & K082326, E=Added under Appendix E

<sup>1</sup> Includes B-Mode and Harmonic (contrast) imaging (HI)

<sup>2</sup> Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)

<sup>3</sup> Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)

<sup>4</sup> Includes B+M, B+M+CM, M+CM, B+CD+M+CM, B+CD+PWD where CD could represent (CD, DPD, PD, or BD)

<sup>5</sup> Color M-Mode (CM)

<sup>6</sup> Abdominal includes renal, GYN/Pelvic

<sup>7</sup> Intra operative include abdominal, thoracic (cardiac) and vascular (PV)

<sup>8</sup> Freehand tissue elasticity

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510(K) K101091

510(K) Number (if known): \_\_\_\_\_

System Name: ZONARE z.one Ultra Ultrasound Diagnostic System

Device Name: Linear Transducer L8-3

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

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Track I & III)	B	M	PWD <sup>2</sup>	CWD	Color Doppler <sup>3</sup>	Combined Modes <sup>4</sup>	Other <sup>5</sup>
General application	Ophthalmic							
	Fetal	P	P	P		P	P	P <sup>5</sup>
	Abdominal <sup>6</sup>	P	P	P		P	P	P <sup>5</sup>
	Intra-operative (Specify) <sup>7</sup>	P	P	P		P	P	P <sup>5</sup>
	Intra-operative (Neuro)	P		P		P	P	P <sup>5</sup>
	Laparoscopic							
	Pediatric	P	P	P		P	P	P <sup>5</sup>
	Small Organ (Thyroid, Breast, Testes, etc.)	P	P	P		P	P	P <sup>5</sup> P <sup>8</sup>
	Neonatal Cephalic	P	P	P		P	P	P <sup>5</sup>
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Conventional)	P	P	P		P	P	P <sup>5,8</sup>
	Musculo-skel. (Superficial)	P	P	P		P	P	P <sup>5,8</sup>
	Intra-luminal							
	Other (Specify) <sup>8</sup> 3D/4D							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vascular	Peripheral Vascular	P	P	P		P	P	P <sup>5</sup> P <sup>8</sup>
	Other (Specify) 3D/4D							

N = new indication; P=previously cleared by the FDA 510(k) K082326, E=Added under Appendix E

<sup>1</sup> Includes B-Mode and Harmonic (contrast) imaging (HI)

<sup>2</sup> Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)

<sup>3</sup> Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)

<sup>4</sup> Includes B+M, B+M+CM, M+CM, B+CD+M+CM, B+CD+PWD where CD could represent (CD, DPD, PD, or BD)

<sup>5</sup> Color M-Mode (CM)

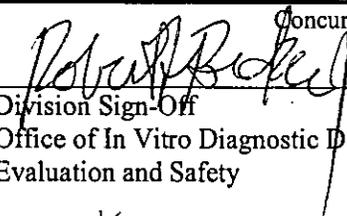
<sup>6</sup> Abdominal includes renal, GYN/Pelvic

<sup>7</sup> Intra operative include abdominal, thoracic (cardiac) and vascular (PV)

<sup>8</sup> Freehand tissue elasticity

Examples may include A-mode, Amplitude Doppler, 3-D imaging, Harmonic imaging, Tissue Motion Doppler, Color velocity imaging

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510(K) K101091

510(K) Number (if known): \_\_\_\_\_

System Name: ZONARE z.one Ultra Ultrasound Diagnostic System

Device Name: Linear Transducer L12-4v

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

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Track I & III)	B	M	PWD <sup>2</sup>	CWD	Color Doppler <sup>3</sup>	Combined Modes <sup>4</sup>	Other <sup>5</sup>
Ophthalmic	Ophthalmic							
General application	Fetal							
	Abdominal							
	Intra-operative (Specify) <sup>7</sup>							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	E	E	E		E	E	
	Small Organ (Thyroid, Breast, Testes, etc.)	E	E	E		E	E	
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Conventional)	E	E	E		E	E	E
	Musculo-skel. (Superficial)	E	E	E		E	E	E
Intra-luminal								
Other (Specify) (3D/4D) (vet use too)	E	E	E		E	E	E	
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral vascular	Peripheral vascular	E	E	E		E	E	E
	Other (Specify)							

N = new indication; P=previously cleared by FDA, E=Added under appendix E,

<sup>1</sup> Includes B-Mode and Harmonic (contrast) imaging (HI)

<sup>2</sup> Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)

<sup>3</sup> Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)

<sup>4</sup> Includes B+M, B+M+CM, M+CM, B+CD+M+CM, B+CD+PWD where CD could represent (CD, DPD, PD, or BD)

<sup>5</sup> Color M-Mode (CM)

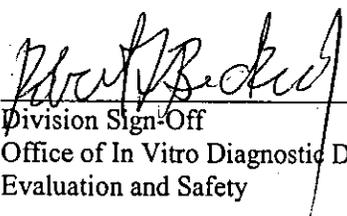
<sup>6</sup> Abdominal includes renal, GYN/Pelvic

<sup>7</sup> Intra operative include abdominal, thoracic (cardiac) and vascular (PV)

<sup>8</sup> Freehand tissue elasticity

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

  
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 Evaluation and Safety

510(K) K101091

510(K) Number (if known): \_\_\_\_\_

System Name: ZONARE z.one Ultra Ultrasound Diagnostic System

Device Name: Linear Transducer L14-5sp

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

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Track I & III)	B	M	PWD <sup>2</sup>	CWD	Color Doppler <sup>3</sup>	Combined Modes <sup>4</sup>	Other <sup>5</sup>
Ophthalmic	Ophthalmic							
General application	Fetal	P	P	P		P	P	P <sup>5</sup>
	Abdominal <sup>6</sup>	P	P	P		P	P	P <sup>5</sup>
	Intra-operative (Specify) <sup>7</sup>	P	P	P		P	P	P <sup>5</sup>
	Intra-operative (Neuro)	P		P		P	P	P <sup>5</sup>
	Laparoscopic							
	Pediatric	P	P	P		P	P	P <sup>5</sup>
	Small Organ (Thyroid, Breast, Testes, etc.)	P	P	P		P	P	P <sup>5</sup> P <sup>8</sup>
	Neonatal Cephalic	P	P	P		P	P	P <sup>5</sup>
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Conventional)	P	P	P		P	P	P <sup>5,8</sup>
	Musculo-skel. (Superficial)	P	P	P		P	P	P <sup>5,8</sup>
	Intra-luminal							
Other (Specify) <sup>8</sup> 3D/4D								
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vascular	Peripheral Vascular	P	P	P		P	P	P <sup>5</sup> P <sup>8</sup>
	Other (Specify) 3D/4D							

N = new indication; P=previously cleared by the FDA 510(k) K082326, E=Added under Appendix E

<sup>1</sup> Includes B-Mode and Harmonic (contrast) imaging (HI)

<sup>2</sup> Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)

<sup>3</sup> Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)

<sup>4</sup> Includes B+M, B+M+CM, M+CM, B+CD+M+CM, B+CD+PWD where CD could represent (CD, DPD, PD, or BD)

<sup>5</sup> Color M-Mode (CM)

<sup>6</sup> Abdominal includes renal, GYN/Pelvic

<sup>7</sup> Intra operative include abdominal, thoracic (cardiac) and vascular (PV)

<sup>8</sup> Freehand tissue elasticity

Examples may include A-mode, Amplitude Doppler, 3-D imaging, Harmonic imaging, Tissue Motion Doppler, Color velocity imaging

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Evaluation and Safety

510(K) K101091

510(K) Number (if known): \_\_\_\_\_

System Name ZONARE z.one Ultra Ultrasound Diagnostic System

Device Name: Linear Transducer L14-5w

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

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Track I & III)	B	M	PWD <sup>2</sup>	CWD	Color Doppler <sup>3</sup>	Combined Modes <sup>4</sup>	Other <sup>5</sup> <sub>8</sub>
Ophthalmic	Ophthalmic							
General application	Fetal	P	P	P		P	P	P <sup>5</sup>
	Abdominal <sup>6</sup>	P	P	P		P	P	P <sup>5</sup>
	Intra-operative (Specify) <sup>7</sup>	P	P	P		P	P	P <sup>5</sup>
	Intra-operative (Neuro)	P		P		P	P	P <sup>5</sup>
	Laparoscopic							
	Pediatric	P	P	P		P	P	P <sup>5</sup>
	Small Organ (Thyroid, Breast, Testes, etc.)	P	P	P		P	P	P <sup>5</sup> P <sup>8</sup>
	Neonatal Cephalic	P	P	P		P	P	P <sup>5</sup>
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Conventional)	P	P	P		P	P	P <sup>5,8</sup>
	Musculo-skel. (Superficial)	P	P	P		P	P	P <sup>5,8</sup>
Intra-luminal								
Other (Specify) <sup>8</sup> 3D/4D								
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vascular	Peripheral Vascular	P	P	P		P	P	P <sup>5</sup> P <sup>8</sup>
	Other (Specify) 3D/4D							

N = new indication; P=previously cleared by the FDA 510(k) K082326, E=Added under Appendix E

<sup>1</sup> Includes B-Mode and Harmonic (contrast) imaging (HI)

<sup>2</sup> Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)

<sup>3</sup> Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)

<sup>4</sup> Includes B+M, B+M+CM, M+CM, B+CD+M+CM, B+CD+PWD where CD could represent (CD, DPD, PD, or BD)

<sup>5</sup> Color M-Mode (CM)

<sup>6</sup> Abdominal includes renal, GYN/Pelvic

<sup>7</sup> Intra operative include abdominal, thoracic (cardiac) and vascular (PV)

<sup>8</sup> Freehand tissue elasticity

Examples may include A-mode, Amplitude Doppler, 3-D imaging, Harmonic imaging, Tissue Motion Doppler, Color velocity imaging

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

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510(K) K101091

510(K) Number (if known): \_\_\_\_\_

System Name: ZONARE z.one Ultra Ultrasound Diagnostic System

Device Name: Tran-Esophageal Transducer: P8-3T

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

Clinical Application		Mode of Operation							
General (Track I Only)	Specific (Track I & III)	B	M	PWD <sup>2</sup>	CWD	Color Doppler <sup>3</sup>	Combined Modes <sup>4</sup>	Other <sup>5</sup>	
General applications	Ophthalmic								
	Fetal								
	Abdominal								
	Intra-operative (Specify) <sup>7</sup>								
	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 <sup>5</sup>
	Musculo-skel. (Conventional)								
	Musculo-skel. (Superficial)								
	Intra-luminal								
Other (Specify) (3D/4D)									
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Trans-esoph. (Cardiac)		P	P	P	P	P	P	P <sup>5</sup>
	Other (Specify)								
Peripheral Vessel	Peripheral Vessel								
	Other (Specify)								

N = new indication; P=previously cleared by FDA 510(k) K082326, E=Appendix E

<sup>1</sup> Includes B-Mode and Harmonic (contrast) imaging (HI)

<sup>2</sup> Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)

<sup>3</sup> Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)

<sup>4</sup> Includes B+M, B+M+CM, M+CM, B+CD+M+CM, B+CD+PWD where CD could represent (CD, DPD, PD, or BD)

<sup>5</sup> Color M-Mode (CM)

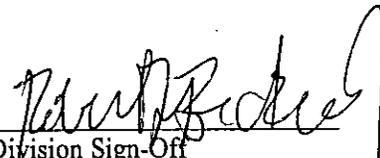
<sup>6</sup> Abdominal includes renal, GYN/Pelvic

<sup>7</sup> Intra operative include abdominal, thoracic (cardiac) and vascular (PV)

<sup>8</sup> Freehand tissue elasticity

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510(K) K101091

510(K) Number (if known): \_\_\_\_\_

System Name: ZONARE z.one Ultra Ultrasound Diagnostic System

Device Name: St. Jude EP ViewFlex PLUS ICE Catheter model # VF-PM Part #09-2005

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

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Track I & III)	B	M	PWD <sup>2</sup>	CWD	Color Doppler <sup>3</sup>	Combined Modes <sup>4</sup>	Other <sup>5</sup>
General application	Ophthalmic							
	Fetal							
	Abdominal							
	Intra-operative (Specify) <sup>7</sup>							
	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)							
	Intra-luminal							
Other (Specify) (3D/4D)								
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Intra-Cardiac)	P	P	P		P		
Peripheral vascular	Peripheral vascular							
	Other (Specify)							

N = new indication; P=previously cleared by FDA 510(k) K031066 & K073709, E=Added under Appendix E

<sup>1</sup> Includes B-Mode and Harmonic (contrast) imaging (HI)

<sup>2</sup> Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)

<sup>3</sup> Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)

<sup>4</sup> Includes B+M, B+M+CM, M+CM, B+CD+M+CM, B+CD+PWD where CD could represent (CD, DPD, PD, or BD)

<sup>5</sup> Color M-Mode (CM)

<sup>6</sup> Abdominal includes renal, GYN/Pelvic

<sup>7</sup> Intra operative include abdominal, thoracic (cardiac) and vascular (PV)

<sup>8</sup> Freehand tissue elasticity

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510(K) K101091

510(K) Number (if known): \_\_\_\_\_

System Name: ZONARE z.one Ultra Ultrasound Diagnostic System

Device Name: A2CW (Common name Pencil Probe)

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

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Track I & III)	B	M	PWD <sup>2</sup>	CWD	Color Doppler <sup>3</sup>	Combined Modes <sup>4</sup>	Other <sup>5</sup>
Ophthalmic	Ophthalmic							
General application	Fetal							
	Abdominal							
	Intra-operative (Specify) <sup>7</sup>							
	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)							
	Intra-luminal							
	Other (Specify) (3D/4D)							
Cardiac	Cardiac Adult					P		
	Cardiac Pediatric					P		
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral vascular	Peripheral vascular							
	Other (Specify)							

N = new indication; P=previously cleared by FDA 510(k) K082326, E=Appendix E

<sup>1</sup> Includes B-Mode and Harmonic (contrast) imaging (HI)

<sup>2</sup> Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)

<sup>3</sup> Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)

<sup>4</sup> Includes B+M, B+M+CM, M+CM, B+CD+M+CM, B+CD+PWD where CD could represent (CD, DPD, PD, or BD)

<sup>5</sup> Color M-Mode (CM)

<sup>6</sup> Abdominal includes renal, GYN/Pelvic

<sup>7</sup> Intra operative include abdominal, thoracic (cardiac) and vascular (PV)

<sup>8</sup> Freehand tissue elasticity

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510(K) K101091

510(K) Number (if known): \_\_\_\_\_

System Name: ZONARE z.one Ultra Ultrasound Diagnostic System

Device Name: A5CW (Common name Pencil Probe)

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

Clinical Application		Mode of Operation							
General (Track I Only)	Specific (Track I & III)	B	M	PWD <sup>2</sup>	CWD	Color Doppler <sup>3</sup>	Combined Modes <sup>4</sup>	Other <sup>5</sup>	
General application	Ophthalmic								
	Fetal								
	Abdominal								
	Intra-operative (Specify) <sup>7</sup>								
	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)								
	Intra-luminal								
	Other (Specify) (3D/4D)								
	Cardiac	Cardiac Adult							
		Cardiac Pediatric							
Trans-esoph. (Cardiac)									
Other (Specify)									
Peripheral vascular	Peripheral vascular				P				
	Other (Specify)								

N = new indication; P=previously cleared by FDA 510(k) K082326, E=Appendix E

<sup>1</sup> Includes B-Mode and Harmonic (contrast) imaging (HI)

<sup>2</sup> Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)

<sup>3</sup> Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)

<sup>4</sup> Includes B+M, B+M+CM, M+CM, B+CD+M+CM, B+CD+PWD where CD could represent (CD, DPD, PD, or BD)

<sup>5</sup> Color M-Mode (CM)

<sup>6</sup> Abdominal includes renal, GYN/Pelvic

<sup>7</sup> Intra operative include abdominal, thoracic (cardiac) and vascular (PV)

<sup>8</sup> Freehand tissue elasticity

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510k Submittal ZONARE Medical Systems, Inc.