ZONARE 510(k) Summary of Safety & Effectiveness

Prepared in accordance with 21 CFR Part 807.92(c)

APR 13 2012

The assigned 510(k) number is: K120703

Applicant Information:

Date Prepared: February 22, 2012

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

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Email lmoore@zonare.com

Device Information:

Trade Name: ZONARE ZS3 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 ZS3 Ultrasound System is a combination of the currently marketed ZONARE z.one Ultra Ultrasound System consisting of a convertible scanner and cart(s) previously cleared on (K082326) (K101091). The ZS3 combines the scanner and cart into a singular unit, which still resembles the currently marketed z.one Ultra Ultrasound system in looks, features and functionalities, including the same software revision, driving both systems.

Device Description: The ZONARE ZS3 is a general purpose diagnostic ultrasound system which consists of a the previous cleared portable scanner integrated into the ZONARE z.one Ultra Smartcart to enable the user to focus on performing patient scans with a more streamline unit. No longer convertible, the ZONARE ZS3 will still be considered a mobile system as it will be lightweight and easy to move from room to room. The new system, which uses the same software base as the currently approved z.one Ultra ultrasound system, will have hardware changes which are minimal, but require some redesign in the cart base in order to put working components of the scanner inside the cart. Otherwise, the user interface and other features/functionalities of the system are substantially equivalent to the ZONARE Ultra Ultrasound System in both indications for use and system functionality. The new ZS3 will be based on the ZONARE's patented zone sonography, and with the scanner's internal components now inside the cart base, the ZS3, without compromising safety and

effectiveness, should improve image quality through a higher signal to noise ratio, as well as support a wider range of future enhancements. Features, such as multi transducer ports will be standard in the system as will an embedded hard drive and DVD. The system will function with the ZONARE Ultra current suite of transducers. 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. There is no difference between the currently cleared ZONARE transducers (K101091) and the transducers as shown in this submission for the ZS3.

The system provides holders for transducer models, and will be offered with battery chargers and other accessories. The modification for this submission includes no new indication for use but does have 1 transducer the C10-3 added as appendix E to the ZONARE z.one Ultra Ultrasound system which will be declared new to this 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; Echo, Intra-Cardiac; Pelvic; Peripheral vascular; harmonic tissue and contrast imaging and Tissue elasticity, Vet and others as stated in 1.3.

Comparison with Predicate Device: With respect to features and applications, the ZONARE ZS3 Ultrasound System, is comparable and substantially equivalent to the currently marketed ZONARE z.one Ultra Ultrasound System, and the additional predicate device listed in predicate devices section in terms of features and functionality. Additionally, the ZONARE ZS3 Ultrasound System and the ZONARE z.one Ultra Ultrasound System have the same important safety and effectiveness features, as well as share the same software, materials, and design/construction as shown in the predicate device comparison table.

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(s) 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

Clinical Tests: Non Required

Conclusion: The device conforms to applicable medical device safety standards and compliance for safety and effectiveness which is verified through defined verification and validation, and market surveillance. Driven by the same software, which is used by the currently marketed ZONARE z.one Ultra Ultrasound System, which has been shown to be safety and effective, the ZONARE ZS3 Ultrasound system is substantially equivalent with respect to safety and effectiveness to devices current cleared for market.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

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

APR 13 2012

Re: K120703
Trade/Device Name: The ZONARE ZS3 Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, ITX, and IYO
Dated: March 28, 2012
Received: March 29, 2012

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 The ZONARE ZS3 Ultrasound System, as described in your premarket notification:

Transducer Model Number

Curvilinear Transducer C4-1
Curvilinear Transducer C6-2
Curvilinear Transducer C9-3
Phased (Sector) Array Transducer C10-3
Curvilinear Transducer C8-3 (3D/4D)
Curvilinear Transducer C9-4t
Phase (Sector) Array Transducer P4-1c
Phased (Sector) Array Transducer P10-4
Endo-Cavity Transducer E9-4
Endo-Cavity Transducer E9-3 (3D)

Linear Transducer L10-5
Linear Transducer L8-3
Linear Transducer L12-4v
Linear Transducer L14-5sp
Linear Transducer L14-5w
Tran-Esophageal Transducer P8-3TEE
St. Jude EP ViewFlex PLUS ICE Catheter model # VF-PM Part #09-2005 (off the shelf)(P9-3ic)

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 Jeffrey Ballyns at (301) 796-6105.

Sincerely Yours,

Janine M. Morris
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):_____

Device Name: **The ZONARE ZS3 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; Echo, Intra-Cardiac; Pelvic; Peripheral vascular; harmonic tissue and contrast imaging and Tissue elasticity.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C

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

Division Sign-Off
Office of In Vitro Diagnostic Devices
Evaluation and Safety
510(K) K120703

Page 1 of ___

1.3 Diagnostic Ultrasound Indications for use

510(K) Number (if known):_____

System Name: ZONARE ZS3 Ultrasound Diagnostic System

Device Name: System 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[2]	CWD *CWD Aux*	Color Doppler[3]	Combined Modes[4]	Other[5, 8]
Ophthalmic	Ophthalmic	N		N		N	N	
General Application	Fetal	N	N	N		N	N	N[5]
	Abdominal	N	N	N		N	N	N[5]
	Intra-operative (Specify)[6]	N	N	N		N	N	N[5]
	Intra-operative (Neuro)	N		N		N	N	N[5]
	Laparoscopic							
	Pediatric	N	N	N		N	N	N[5]
	Pediatric Aux							
	Small Organ (Thyroid, Breast, Testes, etc.)	N	N	N		N	N	N[5] N[8]
	Neonatal Cephalic	N	N	N		N	N	N[5]
	Adult Cephalic	N	N	N		N	N	N[5]
	Trans-rectal	N	N	N		N	N	N[5]
	Trans-vaginal	N	N	N		N	N	N[5]
	Trans-urethral							
	Trans-esoph. (non-Card.)	N	N	N		N	N	N[5]
	Musculo-skel. (Conventional)	N	N	N		N	N	N[5, 8]
	Musculo-skel. (Superficial)	N	N	N		N	N	N[5, 8]
	Intra-luminal							
	Other (Specify) (3D/4D)	N	N	N		N	N	
Cardiac	Cardiac Adult	N[1]	N	N		N	N	N[5]
	Cardia Adult Aux							
	Cardiac Pediatric	N	N	N		N	N	N[5]
	Cardiac Pediatric Aux							
	Trans-esoph. (Cardiac)	N	N	N		N	N	N[5]
	Other (Specify) (3D/4D)	N	N	N		N	N	
	Other (Intra-Cardiac)*	N	N	N		N		
Peripheral vascular	Peripheral Vessel	N	N	N		N	N	N[5] N[8]
	Peripheral Vessel Aux							
	Other (Specify) (3D/4D)	N	N	N		N	N	

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

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

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

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

[4] Includes B+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

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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Office of In Vitro Diagnostic Devices
Evaluation and Safety
510(K) K100703

510(K) Number (if known):_____

System Name: ZONARE ZS3 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[2]	CWD aux	Color Doppler[3]	Combined Modes[4]	Other[5,8]
Ophthalmic	Ophthalmic							
	Fetal	P	P	P		P	P	
	Abdominal	P	P	P		P	P	
	Intra-operative (Specify)[7]							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	P	P	P		P	P	
	Pediatric Aux							
	Small Organ (Thyroid, Breast, Testes, etc.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Conventional)	P	P	P		P		
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other (Specify) (3D/4D) contrast	P	P	P		P	P	
Cardiac	Cardiac Adult	P	P	P		P	P	
	Cardiac Adult Aux							
	Cardiac Pediatric							
	Cardiac Pediatric Aux							
	Trans-esoph. (Cardiac)							
	Other (specify) 3D/4D							
	Other (intra-cardiac)*							
Peripheral vascular	Peripheral Vessel							
	Peripheral Vessel Aux							
	Other (Specify) 3D/4D							

N = new indication; P=previously cleared by FDA 510(k) K082326 & K101091, E=Added under Appendix E

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

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

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

[4] Includes B+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

Prescription Use_____ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____ (21 CFR 801 Subpart C

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Division Sign-Off
Office of In Vitro Diagnostic Devices
Evaluation and Safety
510(K) K120703

510(K) Number (if known):_____

System Name: ZONARE ZS3 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[2]	CWD	Color Doppler[3]	Combined Modes[4]	Other[5, 8]
Ophthalmic	Ophthalmic							
General applications	Fetal	P	P	P		P	P	P[5]
	Abdominal[6]	P	P	P		P	P	P[5]
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	P	P	P		P	P	P[5]
	Small Organ (Thyroid, Breast, Testes, etc.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	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[5]
	Other (Specify)							

N = new indication; P=previously cleared by FDA 510(k) K082326 & K101091, E=Added under Appendix E

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

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

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

[4] Includes B+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

Prescription Use _____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C

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510(K) K120703

510(K) Number (if known):_____

System Name: ZONARE ZS3 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[2]	CWD	Color Doppler[3]	Combined Modes[4]	Other[5, 8]
Ophthalmic	Ophthalmic							
General applications	Fetal	P	P	P		P	P	P[5]
	Abdominal[6]	P	P	P		P	P	P[5]
	Intra-operative (Abdominal)	P	P	P		P	P	P[5]
	Intra-operative (Vascular)	P	P	P		P	P	P[5]
	Laparoscopic							
	Pediatric	P	P	P		P	P	P[5]
	Small Organ (Thyroid, Breast, Testes, etc.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Conventional)	P	P	P		P	P	P[5]
	Musculo-skel. (Superficial)	P	P	P		P	P	P[5]
	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[5]
	Other (Specify)							

N = new indication; P=previously cleared by FDA 510(k) K082326 & K101091, E=Added under Appendix E

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

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

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

[4] Includes B+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

Prescription Use _____ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C

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510(K) K120703

510(K) Number (if known):_____

System Name: ZONARE ZS3 Ultrasound Diagnostic System

Device Name: Phased (Sector) Array Transducer C10-3

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[2]	CWD	Color Doppler[3]	Combined Modes[4]	Other[5,8]
Ophthalmic	Ophthalmic							
General application	Fetal	N	N	N		N	N	N[5]
	Abdominal[6]	N	N	N		N	N	N[5]
	Intra-operative (specify)	N	N	N		N	N	N[5]
	Intra-operative (Neuro)	N	N	N		N	N	N[5]
	Laparoscopic							
	Pediatric	N	N	N		N	N	N[5]
	Small Organ (Thyroid, Breast, Testes, etc.)							
	Neonatal Cephalic	N	N	N		N	N	N[5]
	Adult Cephalic/ trans cranial	N	N	N		N	N	N[5]
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult	N	N	N		N	N	N[5]
	Cardiac Pediatric	N	N	N		N	N	N[5]
	Trans-esoph. (Cardiac)							
	Other (Specify) (3D/4D)							
Peripheral vascular	Peripheral Vascular	N	N	N		N	N	N[5]
	Other (Specify) 3D/4D							

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

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

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

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

[4] Includes B+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

Prescription Use _____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C

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

Division Sign-Off
Office of In Vitro Diagnostic Devices
Evaluation and Safety
510(K) K120703

510(K) Number (if known):_____

System Name: ZONARE ZS3 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[2]	CWD	Color Doppler[3]	Combined Modes[4]	Other[5, 8]
Ophthalmic	Ophthalmic							
General applications	Fetal	P	P	P		P	P	P[5]
	Abdominal[6]	P	P	P		P	P	P[5]
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	P	P	P		P	P	P[5]
	Small Organ (Thyroid, Breast, Testes, etc.)							
	Peonatal 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[5]
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vascular	Peripheral Vascular	P	P	P		P	P	P[5]
	Other (Specify)							

N = new indication; P=previously cleared by FDA 510(k) K101091, E=Added under Appendix E
[1] Includes B-Mode and Harmonic (contrast) imaging (HI)
[2] Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)
[3] Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)
[4] Includes B+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

Prescription Use _____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C

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

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Evaluation and Safety
510(K) K120703

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510(K) Number (if known):_____

System Name: ZONARE ZS3 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[2]	CWD	Color Doppler[3]	Combined Modes[4]	Other[5,8]
Ophthalmic	Ophthalmic							
General application	Fetal							
	Abdominal	P	P	P		P	P	
	Intra-operative (Specify)[7]							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	P	P	P		P	P	
	Small Organ (Thyroid, Breast, Testes, etc.)							
	Neonatal Cephalic	P	P	P		P	P	
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Conventional)	P	P	P		P	P	
	Musculo-skel. (Superficial)	P	P	P		P	P	
	Intra-luminal							
	Other (Specify) (3D/4D) Vet abdominal	P	P	P		P	P	
Cardiac	Cardiac Adult							
	Cardiac Pediatric	P	P	P		P	P	
	Trans-esoph. (Cardiac)							
	Other (Specify) vet cardiac	P	P	P		P	P	
Peripheral vascular	Peripheral vascular							
	Other (Specify)							

N = new indication; P=previously cleared by FDA 510(k) 101091, E=Added under Appendix E
[1] Includes B-Mode and Harmonic (contrast) imaging (HI)
[2] Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)
[3] Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)
[4] Includes B+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

Prescription Use _____ AND/OR Over-The-Counter Use _____
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510(K) Number (if known):_____

System Name: ZONARE ZS3 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[2]	CWD	Color Doppler[3]	Combined Modes[4]	Other[5,8]
Ophthalmic	Ophthalmic							
General application	Fetal	P	P	P		P	P	P[5]
	Abdominal[6]	P	P	P		P	P	P[5]
	Intra-operative (Specify)[7]							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	P	P	P		P	P	P[5]
	Small Organ (Thyroid, Breast, Testes, etc.)							
	Neonatal Cephalic	P	P	P		P	P	P[5]
	Adult Cephalic/ trans cranial	P	P	P		P	P	P[5]
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult	P[1]	P	P		P	P	P[5]
	Cardiac Pediatric	P	P	P		P	P	P[5]
	Trans-esoph. (Cardiac)							
	Other (Specify) (3D/4D)contrast	P	P	P		P	P	P[5]
Peripheral vascular	Peripheral Vascular	P	P	P		P	P	P[5]
	Other (Specify)							

N = new indication; P=previously cleared by the FDA 510(k) K101091, E=Added under Appendix E
[1] Includes B-Mode and Harmonic (contrast) imaging (HI)
[2] Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)
[3] Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)
[4] Includes B+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

Prescription Use _____ AND/OR Over-The-Counter Use _____
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510(K) Number (if known):_____

System Name: ZONARE ZS3 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[2]	CWD	Color Doppler[3]	Combined Modes[4]	Other[5,8]
Ophthalmic	Ophthalmic							
General application	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	P[5]
	Laparoscopic							
	Pediatric	P	P	P		P	P	P[5]
	Small Organ (Thyroid, Breast, Testes, etc.)							
	Neonatal Cephalic	P	P	P		P	P	P[5]
	Adult Cephalic/ trans cranial	P	P	P		P	P	P[5]
	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[5]
	Cardiac Pediatric	P	P	P		P	P	P[5]
	Trans-esoph. (Cardiac)							
	Other (Specify) (3D/4D)							
Peripheral vascular	Peripheral Vascular	P	P	P		P	P	P[5]
	Other (Specify)							

N = new indication; P=previously cleared by the FDA 510(k) K101091, E=Added under Appendix E
[1] Includes B-Mode and Harmonic (contrast) imaging (HI)
[2] Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)
[3] Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)
[4] Includes B+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

Prescription Use _____ AND/OR Over-The-Counter Use _____
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510(K) K120703

510(K) Number (if known):_____

System Name: ZONARE ZS3 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[2]	CWD	Color Doppler[3]	Combined Modes[4],	Other[5, 8]
Ophthalmic	Ophthalmic							
General application	Fetal	P	P	P		P	P	P[5]
	Abdominal							
	Intra-operative (Specify)[7]							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Thyroid, Breast, Testes, etc.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	P	P	P		P	P	P[5]
	Trans-vaginal	P	P	P		P	P	P[5]
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	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) K101091, E=Added under Appendix E
[1] Includes B-Mode and Harmonic (contrast) imaging (HI)
[2] Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)
[3] Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)
[4] Includes B+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

Prescription Use _____ (Part 21 CFR 801 Subpart D)

AND/OR

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

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510(K) Number (if known):_____

System Name: ZONARE ZS3 Ultrasound Diagnostic System

Device Name: Endo-Cavity Transducer E9-3 (3D) {cleared under 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[2]	CWD	Color Doppler[3]	Combined Modes[4]	Other[5, 8]
Ophthalmic	Ophthalmic							
General application	Fetal	P	P	P		P	P	P[5]
	Abdominal							
	Intra-operative (Specify)[7]							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Thyroid, Breast, Testes, etc.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	P	P	P		P	P	P[5]
	Trans-vaginal	P	P	P		P	P	P[5]
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other (Specify) (3D/4D)	P	P	P		P	P	P[5]
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 & K101091, E=Added under Appendix E

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

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

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

[4] Includes B+M, B+M+CM, M+CM, B+CD+M+CM, B+CD+PWD where CD could represent (CD, DPD, PD, or BD)

[5] Color M-Mode (CM)

[6] Abdominal includes renal, GYN/Pelvic

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

[8] Freehand tissue elasticity

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510(K) Number (if known):_____

System Name: ZONARE ZS3 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[2]	CWD	Color Doppler[3]	Combined Modes[4]	Other[5, 8]
Ophthalmic	Ophthalmic	P		P		P	P	
General application	Fetal	P	P	P		P	P	P[5]
	Abdominal[6]	P	P	P		P	P	P[5]
	Intra-operative (Specify)[7]	P	P	P		P	P	P[5]
	Intra-operative (Neuro)	P		P		P	P	P[5]
	Laparoscopic							
	Pediatric	P	P	P		P	P	P[5]
	Small Organ (Thyroid, Breast, Testes, etc.)	P	P	P		P	P	P[5] P[8]
	Neonatal Cephalic	P	P	P		P	P	P[5]
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Conventional)	P	P	P		P	P	P[5, 8]
	Musculo-skel. (Superficial)	P	P	P		P	P	P[5, 8]
	Intra-luminal							
	Other (Specify)[8] (3D/4D)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vascular	Peripheral Vascular	P	P	P		P	P	P[5] P[8]
	Other (Specify) 3D/4D							

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

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

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

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

[4] Includes B+M, B+M+CM, M+CM, B+CD+M+CM, B+CD+PWD where CD could represent (CD, DPD, PD, or BD)

[5] Color M-Mode (CM)

[6] Abdominal includes renal, GYN/Pelvic

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

[8] Freehand tissue elasticity

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510(K) Number (if known):_____

System Name: ZONARE ZS3 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[2]	CWD	Color Doppler[3]	Combined Modes[4]	Other[5, 8]
Ophthalmic	Ophthalmic							
General application	Fetal	P	P	P		P	P	P[5]
	Abdominal[6]	P	P	P		P	P	P[5]
	Intra-operative (Specify)[7]	P	P	P		P	P	P[5]
	Intra-operative (Neuro)	P		P		P	P	P[5]
	Laparoscopic							
	Pediatric	P	P	P		P	P	P[5]
	Small Organ (Thyroid, Breast, Testes, etc.)	P	P	P		P	P	P[5] P[8]
	Neonatal Cephalic	P	P	P		P	P	P[5]
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Conventional)	P	P	P		P	P	P[5, 8]
	Musculo-skel. (Superficial)	P	P	P		P	P	P[5, 8]
	Intra-luminal							
	Other (Specify)[8] 3D/4D							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vascular	Peripheral Vascular	P	P	P		P	P	P[5] P[8]
	Other (Specify) 3D/4D							

N = new indication; P=previously cleared by the FDA 510(k) K082326 & K101091, E=Added under Appendix E

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

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

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

[4] Includes B+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

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

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510(K) K120703

510(K) Number (if known):_____

System Name: ZONARE ZS3 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[2]	CWD	Color Doppler[3]	Combined Modes[4]	Other[5,8]
Ophthalmic	Ophthalmic							
General application	Fetal							
	Abdominal							
	Intra-operative (Specify)[7]							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	P	P	P		P	P	
	Small Organ (Thyroid, Breast, Testes, etc.)	P	P	P		P	P	
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Conventional)	P	P	P		P	P	P
	Musculo-skel. (Superficial)	P	P	P		P	P	P
	Intra-luminal							
	Other (Specify) (3D/4D) (vet use too)	P	P	P		P	P	P
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral vascular	Peripheral vascular	P	P	P		P	P	P
	Other (Specify)							

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

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

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

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

[4] Includes B+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

Prescription Use _____ (Part 21 CFR 801 Subpart D)

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510(K) Number (if known):_____

System Name: ZONARE ZS3 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[2]	CWD	Color Doppler[3]	Combined Modes[4]	Other[5, 8]
Ophthalmic	Ophthalmic							
General application	Fetal	P	P	P		P	P	P[5]
	Abdominal[6]	P	P	P		P	P	P[5]
	Intra-operative (Specify)[7]	P	P	P		P	P	P[5]
	Intra-operative (Neuro)	P		P		P	P	P[5]
	Laparoscopic							
	Pediatric	P	P	P		P	P	P[5]
	Small Organ (Thyroid, Breast, Testes, etc.)	P	P	P		P	P	P[5] P[8]
	Neonatal Cephalic	P	P	P		P	P	P[5]
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Conventional)	P	P	P		P	P	P[5, 8]
	Musculo-skel. (Superficial)	P	P	P		P	P	P[5, 8]
	Intra-luminal							
	Other (Specify)[8] 3D/4D							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vascular	Peripheral Vascular	P	P	P		P	P	P[5] P[8]
	Other (Specify) 3D/4D							

N = new indication; P=previously cleared by the FDA 510(k) K082326 & K101091, E=Added under Appendix E

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

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

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

[4] Includes B+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

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

Prescription Use _____ AND/OR Over-The-Counter Use _____

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

Division Sign-Off
Office of In Vitro Diagnostic Devices
Evaluation and Safety
510(K) K120783

510(K) Number (if known):_____

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

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

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

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

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

[4] Includes B+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

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

Prescription Use _____ (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)

Division Sign-Off
Office of In Vitro Diagnostic Devices
Evaluation and Safety
510(K) K120703

510(K) Number (if known):_____

System Name: ZONARE ZS3 Ultrasound Diagnostic System

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

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[2]	CWD	Color Doppler[3]	Combined Modes[4]	Other[5,8]
Ophthalmic	Ophthalmic							
General applications	Fetal							
	Abdominal							
	Intra-operative (Specify)[7]							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Thyroid, Breast, Testes, etc.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)	P	P	P		P	P	P[5]
	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[5]
	Other (Specify)							
Peripheral Vessel	Peripheral Vessel							
	Other (Specify)							

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

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

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

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

[4] Includes B+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

Prescription Use _____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C

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

Division Sign-Off
Office of In Vitro Diagnostic Devices
Evaluation and Safety

510(K) K120703

510(K) Number (if known):_____

System Name: ZONARE ZS3 Ultrasound Diagnostic System

Device Name: St. Jude EP ViewFlex PLUS ICE Catheter model # VF-PM Part #09-2005 **(off the shelf) (P9-3ic)**

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[2]	CWD	Color Doppler[3]	Combined Modes[4]	Other[5,8]
Ophthalmic	Ophthalmic							
General application	Fetal							
	Abdominal							
	Intra-operative (Specify)[7]							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Thyroid, Breast, Testes, etc.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	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) K101091, ST Jude K 031066 K073709 E=Added under Appendix E

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

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

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

[4] Includes B+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

Prescription Use _____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C

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

Division Sign-Off
Office of In Vitro Diagnostic Devices
Evaluation and Safety

510(K) K120703