510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date:	December 13, 2010
Submitter:	GE Healthcare, GE Medical Systems Ultrasound and Primary Care Diagnostics, LLC 9900 Innovation Dr Wauwatosa, WI 53226
Primary Contact Person:	Bryan Behn Regulatory Affairs Manager GE Healthcare T:(414)721-4214 F:(414)918-8275
Device: Trade Name:	Voluson S6, Voluson S8 Ultrasound System
Common/Usual Name:	Voluson S6, Voluson S8
Classification Names:	Class II
Product Code:	Ultrasonic Pulsed Doppler Imaging System. 21CFR 892.1550 90-IYN Ultrasonic Pulsed Echo Imaging System, 21CFR 892.1560, 90-IYO Diagnostic Ultrasound Transducer, 21 CFR 892.1570, 90-ITX
Predicate Device(s):	K061682 Voluson E8 Diagnostic Ultrasound System K092271 Logiq E9 Diagnostic Ultrasound System K053435 Voluson i Diagnostic Ultrasound System
Device Description:	The subject device consists of a mobile console with keyboard, specialized controls, a color video LCD display with electronic-array transducers. It has the same general appearance, dimensions and weight as the unmodified device, it is a Track 3 general-purpose imaging and analysis system providing real-time digital acquisition, processing and display capability intended for general radiology imaging and evaluation with some cardiology and vascular applications.
Intended Use:	The device is a general-purpose ultrasound system. Specific clinical applications and exam types include: Fetal (Obstetrics); Abdominal (including renal and GYN/pelvic); Pediatric; Small Organ (breast, testes, thyroid, salivary gland, lymph nodes, pediatric and neonatal patients); Neonatal Cephalic; Adult Cephalic; Cardiac (adult and pediatric); Peripheral Vascular (PV); Musculo-skeletal Conventional and Superficial; Transrectal (TR); Transvaginal (TV).

Technology: The Voluson S6, Voluson S8 employs the same fundamental scientific technology as its predicate devices

Determination of Substantial Equivalence:

Summary of Non-Clinical Tests:

The device has been evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness as well as thermal, electrical, electromagnetic, and mechanical safety, and has been found to conform to applicable medical device safety standards. Voluson S6, Voluson S8 and its applications comply with voluntary standards as detailed in Section 9, 11 and 17 of this premarket submission. The following quality assurance measures were applied to the development of the system:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Testing on unit level (Module verification)
- Integration testing (System verification)
- Final Acceptance Testing (Validation)
- Performance testing (Verification)
- Safety testing (Verification)

Transducer materials and other patient contact materials are biocompatible.

Summary of Clinical Tests:

The subject of this premarket submission, Voluson S6, Voluson S8, did not require clinical studies to support substantial equivalence.

Conclusion: GE Healthcare considers the Voluson S6, Voluson S8 to be as safe, as effective, and performance is substantially equivalent to the predicate device(s).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Mr. Bryan Behn
Regulatory Affairs Manager
GE Healthcare
9900 Innovation Drive
WAUWATOSA WI 53226

MAR - 9 2011

Re: K103649
Trade/Device Name: Voluson S6, Voluson S8
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, and ITX
Dated: December 13, 2010
Received: December 15, 2010

Dear Mr. Behn:

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 Voluson S6, Voluson S8, as described in your premarket notification:

Transducer Model Number

RAB4-8-RS
4C-RS
E8C-RS
C1-5-RS
12L-RS
AB2-7-RS
RIC5-9W-RS

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 Lauren Hefner at (301) 796-6881.

Sincerely Yours,

Mary S. Pastel, ScD.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure(s)

510(k) Number (if known):

Device Name: Voluson S6, Voluson S8

Indications for Use:
The device is a general-purpose ultrasound system. Specific clinical applications and exam types include: Fetal (Obstetrics); Abdominal (including renal and GYN/pelvic); Pediatric; Small Organ (breast, testes, thyroid, salivary gland, lymph nodes, pediatric and neonatal patients); Neonatal Cephalic; Adult Cephalic; Cardiac (adult and pediatric); Peripheral Vascular (PV); Musculo-skeletal Conventional and Superficial; Transrectal (TR); Transvaginal (TV).

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

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

(Division Sign-Off)
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety

510(k) Number K103649

Indications for Use Forms

The following forms represent indications with clinical applications and exam types along with the modes of operation for the Voluson S6, Voluson S8 system. Combinations identified "P" for the transducers represents those previously cleared with another GE Ultrasound system. Please see section 11 Table 11.2.1 for information on previous clearance information on these transducers.

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
510K K103606/9

Diagnostic Ultrasound Indications for Use Form
GE Voluson S6/S8 Ultrasound System

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

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics[7]	N	N	N		N	N	N	N	N	N	[5,6,9]
Abdominal[1]	N	N	N		N	N	N	N	N	N	[5,6,9]
Pediatric	N	N	N		N	N	N	N	N	N	[5,6,9]
Small Organ[2]	N	N	N		N	N	N	N	N	N	[5,6,9]
Neonatal Cephalic	N	N	N		N	N	N	N	N	N	[5]
Adult Cephalic	N	N	N		N	N	N	N	N	N	
Cardiac[3]	N	N	N		N	N	N	N	N	N	[5]
Peripheral Vascular	N	N	N		N	N	N	N	N	N	[5,6,9]
Musculo-skeletal Conventional	N	N	N		N	N	N	N	N	N	[5,6,9]
Musculo-skeletal Superficial	N	N	N		N	N	N	N	N	N	[5,6,9]
Other											
Exam Type, Means of Access											
Transesophageal											
Transrectal[8]	N	N	N		N	N	N	N	N	N	[5,6,9]
Transvaginal	N	N	N		N	N	N	N	N	N	[5,6,9]
Transuretheral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA

Notes: [1] Abdominal includes renal, GYN/Pelvic
[2] Small organ includes breast, testes, thyroid, salivary gland, lymph nodes, pediatric and neonatal patients
[3] Cardiac is Adult and Pediatric.
[5] 3D/4D Imaging Mode.
[6] Includes imaging of guidance of biopsy (2D/3D/4D).
[7] Includes infertility monitoring of follicle development.
[8] Includes urology/prostate.
[9] Elastography imaging- Elasticity
[*] Combined modes are B/M, B/Color M, B/PWD, B/Color/PWD, B/PWD

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

Prescription User (Per 21 CFR 801.109)

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Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K103649

Diagnostic Ultrasound Indications for Use Form

GE Voluson S6/S8 with RAB4-8-RS Transducer

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

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics[7]	P	P	P		P	P	P	P	P	P	[5,6]
Abdominal[1]	P	P	P		P	P	P	P	P	P	[5,6]
Pediatric	P	P	P		P	P	P	P	P	P	[5,6]
Small Organ[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]											
Peripheral Vascular											
Musculo-skeletal Conventional	P	P	P		P	P	P	P	P	P	[5,6]
Musculo-skeletal Superficial											
Other											
Exam Type, Means of Access											
Transesophageal											
Transrectal[8]											
Transvaginal											
Transuretheral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA

Notes: [1] Abdominal includes renal, GYN/Pelvic
[2] Small organ includes breast, testes, thyroid, salivary gland, lymph nodes, pediatric and neonatal patients
[3] Cardiac is Adult and Pediatric.
[5] 3D/4D Imaging Mode.
[6] Includes imaging of guidance of biopsy (2D/3D/4D).
[7] Includes infertility monitoring of follicle development.
[8] Includes urology/prostate.
[9] Elastography imaging- Elasticity
[*] Combined modes are B/M, B/Color M, B/PWD, B/Color/PWD, B/PWD

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

Prescription User (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K103649

Diagnostic Ultrasound Indications for Use Form

GE Voluson S6/S8 with 4C-RS Transducer

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

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics[7]	P	P	P		P	P	P	P	P	P	[6]
Abdominal[1]	P	P	P		P	P	P	P	P	P	[6]
Pediatric	P	P	P		P	P	P	P	P	P	[6]
Small Organ[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]											
Peripheral Vascular	P	P	P		P	P	P	P	P	P	[6]
Musculo-skeletal Conventional	P	P	P		P	P	P	P	P	P	[6]
Musculo-skeletal Superficial											
Other											
Exam Type, Means of Access											
Transesophageal											
Transrectal[8]											
Transvaginal											
Transuretheral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA

Notes: [1] Abdominal includes renal, GYN/Pelvic
[2] Small organ includes breast, testes, thyroid, salivary gland, lymph nodes, pediatric and neonatal patients
[3] Cardiac is Adult and Pediatric.
[5] 3D/4D Imaging Mode.
[6] Includes imaging of guidance of biopsy (2D/3D/4D).
[7] Includes infertility monitoring of follicle development.
[8] Includes urology/prostate.
[9] Elastography imaging- Elasticity
[*] Combined modes are B/M, B/Color M, B/PWD, B/Color/PWD, B/PWD

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

Prescription User (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K103649

Diagnostic Ultrasound Indications for Use Form

GE Voluson S6/S8 with E8C-RS Transducer

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

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics[7]	P	P	P		P	P	P	P	P	P	[6]
Abdominal[1]											
Pediatric											
Small Organ[2]											
Neonatal Cephalic	P	P	P		P	P	P	P	P	P	
Adult Cephalic											
Cardiac[3]											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other											
Exam Type, Means of Access											
Transesophageal											
Transrectal[8]	P	P	P		P	P	P	P	P	P	[6]
Transvaginal	P	P	P		P	P	P	P	P	P	[6]
Transuretheral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA

Notes: [1] Abdominal includes renal, GYN/Pelvic
[2] Small organ includes breast, testes, thyroid, salivary gland, lymph nodes, pediatric and neonatal patients
[3] Cardiac is Adult and Pediatric.
[5] 3D/4D Imaging Mode.
[6] Includes imaging of guidance of biopsy (2D/3D/4D).
[7] Includes infertility monitoring of follicle development.
[8] Includes urology/prostate.
[9] Elastography imaging- Elasticity
[*] Combined modes are B/M, B/Color M, B/PWD, B/Color/PWD, B/PWD

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

Prescription User (Per 21 CFR 801.109)

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Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K103649

Diagnostic Ultrasound Indications for Use Form

GE Voluson S6/S8 with C1-5-RS Transducer

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

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics[7]	P	P	P		P	P	P	P	P	P	[6]
Abdominal[1]	P	P	P		P	P	P	P	P	P	[6]
Pediatric	P	P	P		P	P	P	P	P	P	[6]
Small Organ[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]											
Peripheral Vascular											
Musculo-skeletal Conventional	P	P	P		P	P	P	P	P	P	[6]
Musculo-skeletal Superficial											
Other											
Exam Type, Means of Access											
Transesophageal											
Transrectal[8]											
Transvaginal											
Transuretheral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA

Notes: [1] Abdominal includes renal, GYN/Pelvic
[2] Small organ includes breast, testes, thyroid, salivary gland, lymph nodes, pediatric and neonatal patients
[3] Cardiac is Adult and Pediatric.
[5] 3D/4D Imaging Mode.
[6] Includes imaging of guidance of biopsy (2D/3D/4D).
[7] Includes infertility monitoring of follicle development.
[8] Includes urology/prostate.
[9] Elastography imaging- Elasticity
[*] Combined modes are B/M, B/Color M, B/PWD, B/Color/PWD, B/PWD

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

Prescription User (Per 21 CFR 801.109)

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(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K103649

Diagnostic Ultrasound Indications for Use Form

GE Voluson S6/S8 with 12L-RS Transducer

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

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics[7]											
Abdominal[1]											
Pediatric	P	P	P		P	P	P	P	P	P	[6,9]
Small Organ[2]	P	P	P		P	P	P	P	P	P	[6,9]
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]											
Peripheral Vascular	P	P	P		P	P	P	P	P	P	[6,9]
Musculo-skeletal Conventional	P	P	P		P	P	P	P	P	P	[6,9]
Musculo-skeletal Superficial	P	P	P		P	P	P	P	P	P	[6,9]
Other											
Exam Type, Means of Access											
Transesophageal											
Transrectal[8]											
Transvaginal											
Transuretheral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA

Notes: [1] Abdominal includes renal, GYN/Pelvic
[2] Small organ includes breast, testes, thyroid, salivary gland, lymph nodes, pediatric and neonatal patients
[3] Cardiac is Adult and Pediatric.
[5] 3D/4D Imaging Mode.
[6] Includes imaging of guidance of biopsy (2D/3D/4D).
[7] Includes infertility monitoring of follicle development.
[8] Includes urology/prostate.
[9] Elastography imaging- Elasticity
[*] Combined modes are B/M, B/Color M, B/PWD, B/Color/PWD, B/PWD

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

Prescription User (Per 21 CFR 801.109)

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Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K103649

Diagnostic Ultrasound Indications for Use Form

GE Voluson S6/S8 with AB2-7-RS Transducer

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

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics[7]	P	P	P		P	P	P	P	P	P	[6]
Abdominal[1]	P	P	P		P	P	P	P	P	P	[6]
Pediatric	P	P	P		P	P	P	P	P	P	[6]
Small Organ[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]											
Peripheral Vascular											
Musculo-skeletal Conventional	P	P	P		P	P	P	P	P	P	[6]
Musculo-skeletal Superficial											
Other											
Exam Type, Means of Access											
Transesophageal											
Transrectal[8]											
Transvaginal											
Transuretheral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA

Notes: [1] Abdominal includes renal, GYN/Pelvic
[2] Small organ includes breast, testes, thyroid, salivary gland, lymph nodes, pediatric and neonatal patients
[3] Cardiac is Adult and Pediatric.
[5] 3D/4D Imaging Mode.
[6] Includes imaging of guidance of biopsy (2D/3D/4D).
[7] Includes infertility monitoring of follicle development.
[8] Includes urology/prostate.
[9] Elastography imaging- Elasticity
[*] Combined modes are B/M, B/Color M, B/PWD, B/Color/PWD, B/PWD

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

Prescription User (Per 21 CFR 801.109)

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Office of In Vitro Diagnostic Device Evaluation and Safety

510K K103649

Diagnostic Ultrasound Indications for Use Form

GE Voluson S6/S8 with RIC5-9W-RS Transducer

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

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other (Notes)
Ophthalmic											
Fetal / Obstetrics[7]	P	P	P		P	P	P	P	P	P	[5,6]
Abdominal[1]											
Pediatric											
Small Organ[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other											
Exam Type, Means of Access											
Transesophageal											
Transrectal[8]	P	P	P		P	P	P	P	P	P	[5,6]
Transvaginal	P	P	P		P	P	P	P	P	P	[5,6]
Transuretheral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA

Notes: [1] Abdominal includes renal, GYN/Pelvic
[2] Small organ includes breast, testes, thyroid, salivary gland, lymph nodes, pediatric and neonatal patients
[3] Cardiac is Adult and Pediatric.
[5] 3D/4D Imaging Mode.
[6] Includes imaging of guidance of biopsy (2D/3D/4D).
[7] Includes infertility monitoring of follicle development.
[8] Includes urology/prostate.
[9] Elastography imaging- Elasticity
[*] Combined modes are B/M, B/Color M, B/PWD, B/Color/PWD, B/PWD

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

Prescription User (Per 21 CFR 801.109)

Mary S Pastel
(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K103649