



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

MEDISONO, LLC
% Jorge Millan, Ph.D.
Regulatory Affairs Director
HIATEC
601 West 20 Street
HIALEAH FL 33010

May 17, 2017

Re: K170078

Trade/Device Name: Medisono Color Doppler Ultrasound System, models P11 Portable, P11 EXPERT Portable, P12 Trolley, P12 Expert, P25 Trolley, and P25 Expert Trolley

Regulation Number: 21 CFR 892.1550

Regulation Name: Ultrasonic pulsed doppler imaging system

Regulatory Class: II

Product Code: IYN, IYO, ITX

Dated: March 1, 2017

Received: March 6, 2017

Dear Dr. Millan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, “Misbranding by reference to premarket notification” (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH’s Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

 For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K170078

Device Name

Medisono Color Doppler Ultrasound System, models P11 Portable, P11 EXPERT Portable, P12 Trolley, P12 Expert, P25 Trolley, and P25 Expert Trolley.

Indications for Use (Describe)

The Medisono Color Doppler Ultrasound System, models P11 Portable, P11 EXPERT Portable, P12 Trolley, P12 Expert, P25 Trolley, and P25 Expert Trolley are general purpose ultrasonic imaging instruments intended for use by a qualified physician for evaluation of Fetal, Abdominal, Pediatric, Small Organ (breast, testes, thyroid), Cephalic (neonatal and adult), Trans-rectal, Trans-vaginal, Peripheral Vascular, Musculo-skeletal (Conventional and Superficial), Cardiac (neonatal and adult), OB/Gyn and Urology.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

**Diagnostic Ultrasound Indications for Use Form
P11 Portable Ultrasonic Diagnostic Imaging System**

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

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Power	Combined (Specify) ^[1]	Other (Specify) ^{[2][3]}
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal	N	N	N		N	N	Note 1	Note 2,4,5
	Abdominal	N	N	N		N	N	Note 1	Note 2,4,5
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric	N	N	N		N	N	Note 1	Note 2,4
	Small Organ (Specify) *	N	N	N		N	N	Note 1	Note 2,4,6
	Neonatal Cephalic	N	N	N	N	N	N	Note 1	Note 2,4,6
	Adult Cephalic	N	N	N	N	N	N	Note 1	Note 2,4,6
	Trans-rectal	N	N	N		N	N	Note 1	Note 2,4
	Trans-vaginal	N	N	N		N	N	Note 1	Note 2,4
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)	N	N	N		N	N	Note 1	Note 2,4
	Musculo-skeletal (Superficial)	N	N	N		N	N	Note 1	Note 2,4
	Intravascular								
	Other (Ob/GYN)	N	N	N		N	N	Note 1	Note 2,4,5
Cardiac	Cardiac Adult	N	N	N	N	N	N	Note 1	Note 2,3,4
	Cardiac Pediatric	N	N	N	N	N	N	Note 1	Note 2,3,4
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	Note 1	Note 2,4
	Other (Urology)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M

Note 1: Other Combined includes: B/M; B/THI; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonics, The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form P11 Portable with 2PI Phase Array Transducer

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

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Power	Combined (Specify) ^[1]	Other (Specify) ^{[2][3]}
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal								
	Abdominal								
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric	N	N	N		N	N	Note 1	Note 2,4
	Small Organ (Specify) *								
	Neonatal Cephalic	N	N	N	N	N	N	Note 1	Note 2,4,6
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric	N	N	N	N	N	N	Note 1	Note 2,3.4
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Urology)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M

Note 1: Other Combined includes: B/M; B/THI; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonics, The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form P11 Portable with 5PI Phase Array Transducer

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

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Power	Combined (Specify) ^[1]	Other (Specify) ^{[2][3]}
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal								
	Abdominal								
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric	N	N	N		N	N	Note 1	Note 2,4
	Small Organ (Specify) *								
	Neonatal Cephalic	N	N	N	N	N	N	Note 1	Note 2,4,6
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric	N	N	N	N	N	N	Note 1	Note 2,3.4
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Urology)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M

Note 1: Other Combined includes: B/M; B/THI; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonics, The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form
P11 Portable with 6V1 Micro-curved Array Transducer

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

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Power	Combined (Specify) ^[1]	Other (Specify) ^{[2][3]}
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal								
	Abdominal								
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify) *								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal	N	N	N		N	N	Note 1	Note 2,4
	Trans-vaginal	N	N	N		N	N	Note 1	Note 2,4
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Urology)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M

Note 1: Other Combined includes: B/M; B/THI; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonics, The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ breast, thyroid, testes

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form
P11 Portable with 6V3 Micro-curved Array Transducer

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

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Power	Combined (Specify) ^[1]	Other (Specify) ^{[2][3]}
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal								
	Abdominal								
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify) *								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal	N	N	N		N	N	Note 1	Note 2,4
	Trans-vaginal	N	N	N		N	N	Note 1	Note 2,4
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Urology)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M

Note 1: Other Combined includes: B/M; B/THI; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonics, The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ breast, thyroid, testes

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form

P11 Portable with EC9-5 Micro-curved Array Transducer

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

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Power	Combined (Specify) ^[1]	Other (Specify) ^{[2][3]}
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal								
	Abdominal								
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify) *								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal	N	N	N		N	N	Note 1	Note 2,4
	Trans-vaginal	N	N	N		N	N	Note 1	Note 2,4
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Urology)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M

Note 1: Other Combined includes: B/M; B/THI; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonics, The feature does not use contrast agents

Note 3: TDI

Note 4: 3D

Note 5: 4D

Note 6: Small Organ breast, thyroid, testes

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form
P11 Portable with C611 Micro-curved Array Transducer

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

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Power	Combined (Specify) ^[1]	Other (Specify) ^{[2][3]}
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal								
	Abdominal	N	N	N		N	N	Note 1	Note 2,4
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric	N	N	N		N	N	Note 1	Note 2,4
	Small Organ (Specify) *								
	Neonatal Cephalic	N	N	N		N	N	Note 1	Note 2,3,4
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric	N	N	N		N	N	Note 1	Note 2,3,4
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Urology)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M

Note 1: Other Combined includes: B/M; B/THI; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonics, The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ breast, thyroid, testes

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form
P11 Portable with C611 Micro-curved Array Transducer

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

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Power	Combined (Specify) ^[1]	Other (Specify) ^{[2][3]}
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal								
	Abdominal	N	N	N		N	N	Note 1	Note 2,4
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric	N	N	N		N	N	Note 1	Note 2,4
	Small Organ (Specify) *								
	Neonatal Cephalic	N	N	N		N	N	Note 1	Note 2,3,4
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric	N	N	N		N	N	Note 1	Note 2,3,4
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Urology)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M

Note 1: Other Combined includes: B/M; B/THI; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonics, The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ breast, thyroid, testes

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

**Diagnostic Ultrasound Indications for Use Form
P11 Portable with C362 Curved Array Transducer**

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

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Power	Combined (Specify) ^[1]	Other (Specify) ^{[2][3]}
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal	N	N	N		N	N	Note 1	Note 2,4
	Abdominal	N	N	N		N	N	Note 1	Note 2,4
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify) *								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)	N	N	N		N	N	Note 1	Note 2,4
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Urology)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M

Note 1: Other Combined includes: B/M; B/THI; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonics, The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ breast, thyroid, testes

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

**Diagnostic Ultrasound Indications for Use Form
P11 Portable with C344 Curved Array Transducer**

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

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Power	Combined (Specify) ^[1]	Other (Specify) ^{[2][3]}
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal	N	N	N		N	N	Note 1	Note 2,4
	Abdominal	N	N	N		N	N	Note 1	Note 2,4
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify) *								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)	N	N	N		N	N	Note 1	Note 2,4
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Urology)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M

Note 1: Other Combined includes: B/M; B/THI; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonics, The feature does not use contrast agents

Note 3: TDI

Note 4: 3D

Note 5: 4D

Note 6: Small Organ breast, thyroid, testes

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form
P11 Portable with VC6-2 Curved Array Transducer

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

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Power	Combined (Specify) ^[1]	Other (Specify) ^{[2][3]}
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal	N	N	N		N	N	Note 1	Note 2,4
	Abdominal	N	N	N		N	N	Note 1	Note 2,4
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify) *								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)	N	N	N		N	N	Note 1	Note 2,4
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Urology)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M

Note 1: Other Combined includes: B/M; B/THI; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonics, The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ breast, thyroid, testes

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form
P11 Portable with L743 Curved Array Transducer

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

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Power	Combined (Specify) ^[1]	Other (Specify) ^{[2][3]}
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal								
	Abdominal								
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify) *	N	N	N		N	N	Note 1	Note 2,4
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)	N	N	N		N	N	Note 1	Note 2,4
	Musculo-skeletal (Superficial)	N	N	N		N	N	Note 1	Note 2,4
	Intravascular								
	Other (Ob/GYN)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)	N	N	N		N	N	Note 1	Note 2,4
Peripheral Vessel	Peripheral vessel								
	Other (Urology)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M

Note 1: Other Combined includes: B/M; B/THI; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonics, The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ breast, thyroid, testes

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form
P11 Portable with L741 Linear Array Transducer

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

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Power	Combined (Specify) ^[1]	Other (Specify) ^{[2][3]}
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal								
	Abdominal								
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify) *	N	N	N		N	N	Note 1	Note 2,4
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)	N	N	N		N	N	Note 1	Note 2,4
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	Note 1	Note 2,4
	Other (Urology)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M

Note 1: Other Combined includes: B/M; B/THI; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonics, The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ breast, thyroid, testes

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form
P11 Portable with L742 Linear Array Transducer

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

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Power	Combined (Specify) ^[1]	Other (Specify) ^{[2][3]}
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal								
	Abdominal								
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify) *	N	N	N		N	N	Note 1	Note 2,4
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)	N	N	N		N	N	Note 1	Note 2,4
	Musculo-skeletal (Superficial)	N	N	N		N	N	Note 1	Note 2,4
	Intravascular								
	Other (Ob/GYN)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	Note 1	Note 2,4
	Other (Urology)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M

Note 1: Other Combined includes: B/M; B/THI; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonics, The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ breast, thyroid, testes

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form
P11 Expert Ultrasonic Diagnostic Imaging System

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

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Power	Combined (Specify) ^[1]	Other (Specify) ^{[2][3]}
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal	N	N	N		N	N	Note 1	Note 2,4,5
	Abdominal	N	N	N		N	N	Note 1	Note 2,4,5
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric	N	N	N		N	N	Note 1	Note 2,4
	Small Organ (Specify) *	N	N	N		N	N	Note 1	Note 2,4,5
	Neonatal Cephalic	N	N	N	N	N	N	Note 1	Note 2,3,4
	Adult Cephalic	N	N	N	N	N	N	Note 1	Note 2,3,4
	Trans-rectal	N	N	N		N	N	Note 1	Note 2,4
	Trans-vaginal	N	N	N		N	N	Note 1	Note 2,4
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)	N	N	N		N	N	Note 1	Note 2,4
	Musculo-skeletal (Superficial)	N	N	N		N	N	Note 1	Note 2,4
	Intravascular								
	Other (Ob/GYN)	N	N	N		N	N	Note 1	Note 2,4,5
Cardiac	Cardiac Adult	N	N	N	N	N	N	Note 1	Note 2,3,4
	Cardiac Pediatric	N	N	N	N	N	N	Note 1	Note 2,3,4
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	Note 1	Note 2,4
	Other (Urology)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M

Note 1: Other Combined includes: B/M; B/THI; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonics, The feature does not use contrast agents

Note 3: TDI

Note 4: 3D

Note 5: 4D

Note 6: Small Organ breast, thyroid, testes

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form
P11 Expert with 2P1 Phase Array Transducer

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

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Power	Combined (Specify) ^[1]	Other (Specify) ^{[2][3]}
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal								
	Abdominal	N	N	N		N	N	Note 1	Note 2,4
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify) *	N	N	N		N	N	Note 1	Note 2,4
	Neonatal Cephalic	N	N	N		N	N	Note 1	Note 2,4
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
Cardiac	Cardiac Adult	N	N	N		N	N	Note 1	Note 2,4
	Cardiac Pediatric	N	N	N		N	N	Note 1	Note 2,4
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Urology)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M

Note 1: Other Combined includes: B/M; B/THI; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonics, The feature does not use contrast agents

Note 3: TDI

Note 4: 3D

Note 5: 4D

Note 6: Small Organ breast, thyroid, testes

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form
P11 Expert with 2P2 Phase Array Transducer

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

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Power	Combined (Specify) ^[1]	Other (Specify) ^{[2][3]}
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal								
	Abdominal	P	P	P		P	P	Note 1	Note 2,4
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify) *	P	P	P		P	P	Note 1	Note 2,3,4
	Neonatal Cephalic	P	P	P		P	P	Note 1	Note 2,3,4
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
Cardiac	Cardiac Adult	P	P	P		P	P	Note 1	Note 2,3,4
	Cardiac Pediatric	P	P	P		P	P	Note 1	Note 2,3,4
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Urology)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M

Note 1: Other Combined includes: B/M; B/THI; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonics, The feature does not use contrast agents

Note 3: TDI

Note 4: 3D

Note 5: 4D

Note 6: Small Organ breast, thyroid, testes

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form P11 Expert with 3P1 Phase Array Transducer

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

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Power	Combined (Specify) ^[1]	Other (Specify) ^{[2][3]}
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal								
	Abdominal	P	P	P		P	P	Note 1	Note 2,4
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify) *	P	P	P		P	P	Note 1	Note 2,3,4
	Neonatal Cephalic	P	P	P		P	P	Note 1	Note 2,3,4
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
Cardiac	Cardiac Adult	P	P	P		P	P	Note 1	Note 2,3,4
	Cardiac Pediatric	P	P	P		P	P	Note 1	Note 2,3,4
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Urology)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M

Note 1: Other Combined includes: B/M; B/THI; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonics, The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ breast, thyroid, testes

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form P11 Experts with 5P1 Phase Array Transducer

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

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Power	Combined (Specify) ^[1]	Other (Specify) ^{[2][3]}
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal								
	Abdominal								
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric	N	N	N		N	N	Note 1	Note 2,4
	Small Organ (Specify) *								
	Neonatal Cephalic	N	N	N	N	N	N	Note 1	Note 2,3,4
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric	N	N	N	N	N	N	Note 1	Note 2,3,4
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Urology)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M

Note 1: Other Combined includes: B/M; B/THI; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonics, The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ breast, thyroid, testes

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form P11 Experts with 5P2 Phase Array Transducer

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

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Power	Combined (Specify) ^[1]	Other (Specify) ^{[2][3]}
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal								
	Abdominal								
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	Note 1	Note 2,4
	Small Organ (Specify) *								
	Neonatal Cephalic	P	P	P	P	P	P	Note 1	Note 2,3,4
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric	P	P	P		P	P	Note 1	Note 2,3,4
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Urology)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M

Note 1: Other Combined includes: B/M; B/THI; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonics, The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ breast, thyroid, testes

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form
P11 Experts with 8P1 Phase Array Transducer

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

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Power	Combined (Specify) ^[1]	Other (Specify) ^{[2][3]}
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal								
	Abdominal								
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	Note 1	Note 2,4
	Small Organ (Specify) *								
	Neonatal Cephalic	P	P	P	P	P	P	Note 1	Note 2,3,4
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric	P	P	P		P	P	Note 1	Note 2,3,4
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Urology)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M

Note 1: Other Combined includes: B/M; B/THI; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonics, The feature does not use contrast agents

Note 3: TDI

Note 4: 3D

Note 5: 4D

Note 6: Small Organ breast, thyroid, testes

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form
P11 Experts with C611 Micro-curved Array Transducer

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

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Power	Combined (Specify) ^[1]	Other (Specify) ^{[2][3]}
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal								
	Abdominal	N	N	N		N	N	Note 1	Note 2,4
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric	N	N	N		N	N	Note 1	Note 2,4
	Small Organ (Specify) *								
	Neonatal Cephalic	N	N	N	N	N	N	Note 1	Note 2,3,4
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric	N	N	N	N	N	N	Note 1	Note 2,3,4
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Urology)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M

Note 1: Other Combined includes: B/M; B/THI; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonics, The feature does not use contrast agents

Note 3: TDI

Note 4: 3D

Note 5: 4D

Note 6: Small Organ breast, thyroid, testes

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form
P11 Experts with C311 Micro-curved Array Transducer

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

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Power	Combined (Specify) ^[1]	Other (Specify) ^{[2][3]}
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal								
	Abdominal	N	N	N		N	N	Note 1	Note 2,4
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify) *								
	Neonatal Cephalic								
	Adult Cephalic	N	N	N	N	N	N	Note 1	Note 2,3,4
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
Cardiac	Cardiac Adult	N	N	N	N	N	N	Note 1	Note 2,3,4
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Urology)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M

Note 1: Other Combined includes: B/M; B/THI; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonics, The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ breast, thyroid, testes

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form
P11 Experts with 6V1 Micro-curved Array Transducer

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

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Power	Combined (Specify) ^[1]	Other (Specify) ^{[2][3]}
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal								
	Abdominal								
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify) *								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal	P	P	P		P	P	Note 1	Note 2,4
	Trans-vaginal	P	P	P		P	P	Note 1	Note 2,4
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Urology)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M

Note 1: Other Combined includes: B/M; B/THI; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonics, The feature does not use contrast agents

Note 3: TDI

Note 4: 3D

Note 5: 4D

Note 6: Small Organ breast, thyroid, testes

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form
P11 Experts with 6V3 Micro-curved Array Transducer

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

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Power	Combined (Specify) ^[1]	Other (Specify) ^{[2][3]}
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal								
	Abdominal								
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify) *								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal	P	P	P		P	P	Note 1	Note 2,4
	Trans-vaginal	P	P	P		P	P	Note 1	Note 2,4
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Urology)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M

Note 1: Other Combined includes: B/M; B/THI; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonics, The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ breast, thyroid, testes

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form
P11 Experts with EC9-5 Micro-curved Array Transducer

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

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Power	Combined (Specify) ^[1]	Other (Specify) ^{[2][3]}
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal								
	Abdominal								
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify) *								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal	N	N	N		N	N	Note 1	Note 2,4
	Trans-vaginal	N	N	N		N	N	Note 1	Note 2,4
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Urology)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M

Note 1: Other Combined includes: B/M; B/THI; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonics, The feature does not use contrast agents

Note 3: TDI

Note 4: 3D

Note 5: 4D

Note 6: Small Organ breast, thyroid, testes

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form
P11 Experts with BCC9-5 Micro-curved Array Transducer

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

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Power	Combined (Specify) ^[1]	Other (Specify) ^{[2][3]}
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal								
	Abdominal								
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify) *								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal	N	N	N		N	N	Note 1	Note 2,4
	Trans-vaginal	N	N	N		N	N	Note 1	Note 2,4
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Urology)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M

Note 1: Other Combined includes: B/M; B/THI; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonics, The feature does not use contrast agents

Note 3: TDI

Note 4: 3D

Note 5: 4D

Note 6: Small Organ breast, thyroid, testes

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form
P11 Experts with BCL10-5 Biplane Array Transducer

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

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Power	Combined (Specify) ^[1]	Other (Specify) ^{[2][3]}
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal								
	Abdominal								
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify) *								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal	N	N	N		N	N	Note 1	Note 2,4
	Trans-vaginal	N	N	N		N	N	Note 1	Note 2,4
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Urology)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M

Note 1: Other Combined includes: B/M; B/THI; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonics, The feature does not use contrast agents

Note 3: TDI

Note 4: 3D

Note 5: 4D

Note 6: Small Organ breast, thyroid, testes

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form
P11 Experts with C344 Curved Array Transducer

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

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Power	Combined (Specify) ^[1]	Other (Specify) ^{[2][3]}
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal	P	P	P		P	P	Note 1	Note 2,4
	Abdominal	P	P	P		P	P	Note 1	Note 2,4
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify) *								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)	P	P	P		P	P	Note 1	Note 2,4
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Urology)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M

Note 1: Other Combined includes: B/M; B/THI; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonics, The feature does not use contrast agents

Note 3: TDI

Note 4: 3D

Note 5: 4D

Note 6: Small Organ breast, thyroid, testes

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

**Diagnostic Ultrasound Indications for Use Form
P11 Experts with C353 Curved Array Transducer**

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

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Power	Combined (Specify) ^[1]	Other (Specify) ^{[2][3]}
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal	P	P	P		P	P	Note 1	Note 2,4
	Abdominal	P	P	P		P	P	Note 1	Note 2,4
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify) *								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)	P	P	P		P	P	Note 1	Note 2,4
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Urology)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M

Note 1: Other Combined includes: B/M; B/THI; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonics, The feature does not use contrast agents

Note 3: TDI

Note 4: 3D

Note 5: 4D

Note 6: Small Organ breast, thyroid, testes

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

**Diagnostic Ultrasound Indications for Use Form
P11 Experts with C354 Curved Array Transducer**

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

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Power	Combined (Specify) ^[1]	Other (Specify) ^{[2][3]}
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal	N	N	N		N	N	Note 1	Note 2,4
	Abdominal	N	N	N		N	N	Note 1	Note 2,4
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify) *								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)	N	N	N		N	N	Note 1	Note 2,4
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Urology)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M

Note 1: Other Combined includes: B/M; B/THI; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonics, The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ breast, thyroid, testes

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

**Diagnostic Ultrasound Indications for Use Form
P11 Experts with C342 Curved Array Transducer**

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

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Power	Combined (Specify) ^[1]	Other (Specify) ^{[2][3]}
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal								
	Abdominal	N	N	N		N	N	Note 1	Note 2,4
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric	N	N	N		N	N	Note 1	Note 2,4
	Small Organ (Specify) *								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Urology)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M

Note 1: Other Combined includes: B/M; B/THI; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonics, The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ breast, thyroid, testes

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

**Diagnostic Ultrasound Indications for Use Form
P11 Experts with C362 Curved Array Transducer**

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

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Power	Combined (Specify) ^[1]	Other (Specify) ^{[2][3]}
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal	N	N	N		N	N	Note 1	Note 2,4
	Abdominal	N	N	N		N	N	Note 1	Note 2,4
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify) *								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)	N	N	N		N	N	Note 1	Note 2,4
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Urology)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M

Note 1: Other Combined includes: B/M; B/THI; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonics, The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ breast, thyroid, testes

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

**Diagnostic Ultrasound Indications for Use Form
P11 Experts with C322 Curved Array Transducer**

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

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Power	Combined (Specify) ^[1]	Other (Specify) ^{[2][3]}
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal	P	P	P		P	P	Note 1	Note 2,4
	Abdominal	P	P	P		P	P	Note 1	Note 2,4
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify) *								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)	P	P	P		P	P	Note 1	Note 2,4
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Urology)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M

Note 1: Other Combined includes: B/M; B/THI; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonics, The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ breast, thyroid, testes

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

**Diagnostic Ultrasound Indications for Use Form
P11 Experts with VC6-2 Curved Array Transducer**

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

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Power	Combined (Specify) ^[1]	Other (Specify) ^{[2][3]}
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal	P	P	P		P	P	Note 1	Note 2,4
	Abdominal	P	P	P		P	P	Note 1	Note 2,4
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify) *								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)	P	P	P		P	P	Note 1	Note 2,4
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Urology)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M

Note 1: Other Combined includes: B/M; B/THI; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonics, The feature does not use contrast agents

Note 3: TDI

Note 4: 3D

Note 5: 4D

Note 6: Small Organ breast, thyroid, testes

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

**Diagnostic Ultrasound Indications for Use Form
P11 Experts with L741 Linear Array Transducer**

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

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Power	Combined (Specify) ^[1]	Other (Specify) ^{[2][3]}
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal								
	Abdominal								
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify) *	P	P	P		P	P	Note 1	Note 2,4,6
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)	P	P	P		P	P	Note 1	Note 2,4
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel	P	P	P		P	P	Note 1	Note 2,4
	Other (Urology)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M

Note 1: Other Combined includes: B/M; B/THI; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonics, The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ breast, thyroid, testes

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

**Diagnostic Ultrasound Indications for Use Form
P11 Experts with L742 Linear Array Transducer**

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

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Power	Combined (Specify) ^[1]	Other (Specify) ^{[2][3]}
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal								
	Abdominal								
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify) *	P	P	P		P	P	Note 1	Note 2,4,6
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)	P	P	P		P	P	Note 1	Note 2,4
	Musculo-skeletal (Superficial)	P	P	P		P	P	Note 1	Note 2,4
	Intravascular								
	Other (Ob/GYN)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel	P	P	P		P	P	Note 1	Note 2,4
	Other (Urology)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M

Note 1: Other Combined includes: B/M; B/THI; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonics, The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ breast, thyroid, testes

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

**Diagnostic Ultrasound Indications for Use Form
P11 Experts with L743 Linear Array Transducer**

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

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Power	Combined (Specify) ^[1]	Other (Specify) ^{[2][3]}
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal								
	Abdominal								
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify) *	N	N	N		N	N	Note 1	Note 2,4,6
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)	N	N	N		N	N	Note 1	Note 2,4
	Musculo-skeletal (Superficial)	N	N	N		N	N	Note 1	Note 2,4
	Intravascular								
	Other (Ob/GYN)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	Note 1	Note 2,4
	Other (Urology)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M

Note 1: Other Combined includes: B/M; B/THI; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonics, The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ breast, thyroid, testes

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

**Diagnostic Ultrasound Indications for Use Form
P11 Experts with L752 Linear Array Transducer**

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

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Power	Combined (Specify) ^[1]	Other (Specify) ^{[2][3]}
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal								
	Abdominal								
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify) *	P	P	P		P	P	Note 1	Note 2,4,6
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)	P	P	P		P	P	Note 1	Note 2,4
	Musculo-skeletal (Superficial)	P	P	P		P	P	Note 1	Note 2,4
	Intravascular								
	Other (Ob/GYN)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel	P	P	P		P	P	Note 1	Note 2,4
	Other (Urology)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M

Note 1: Other Combined includes: B/M; B/THI; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonics, The feature does not use contrast agents

Note 3: TDI

Note 4: 3D

Note 5: 4D

Note 6: Small Organ breast, thyroid, testes

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

**Diagnostic Ultrasound Indications for Use Form
P11 Experts with 10L1 Linear Array Transducer**

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

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Power	Combined (Specify) ^[1]	Other (Specify) ^{[2][3]}
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal								
	Abdominal								
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify) *	N	N	N		N	N	Note 1	Note 2,4,6
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)	N	N	N		N	N	Note 1	Note 2,4
	Musculo-skeletal (Superficial)	N	N	N		N	N	Note 1	Note 2,4
	Intravascular								
	Other (Ob/GYN)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	Note 1	Note 2,4
	Other (Urology)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M

Note 1: Other Combined includes: B/M; B/THI; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonics, The feature does not use contrast agents

Note 3: TDI

Note 4: 3D

Note 5: 4D

Note 6: Small Organ breast, thyroid, testes

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form P12 Trolley Ultrasonic Diagnostic Imaging System

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

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Power	Combined (Specify) ^[1]	Other (Specify) ^{[2][3]}
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal	N	N	N		N	N	Note 1	Note 2,4,6
	Abdominal	N	N	N		N	N	Note 1	Note 2,4,6
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric	N	N	N		N	N	Note 1	Note 2
	Small Organ (Specify) *	N	N	N		N	N	Note 1	Note 2,5
	Neonatal Cephalic	N	N	N	N	N	N	Note 1	Note 2,3
	Adult Cephalic	N	N	N	N	N	N	Note 1	Note 2,3
	Trans-rectal	N	N	N		N	N	Note 1	Note 2
	Trans-vaginal	N	N	N		N	N	Note 1	Note 2
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)	N	N	N		N	N	Note 1	Note 2
	Musculo-skeletal (Superficial)	N	N	N		N	N	Note 1	Note 2
	Intravascular								
	Other (Ob/GYN)	N	N	N		N	N	Note 1	Note 2,4
Cardiac	Cardiac Adult	N	N	N	N	N	N	Note 1	Note 2,3
	Cardiac Pediatric	N	N	N	N	N	N	Note 1	Note 2,3
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	Note 1	Note 2
	Other (Urology)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M

Note 1: Other Combined includes: B/M; B/THI; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonics, The feature does not use contrast agents

Note 3: TDI Note 4: 4D

Note 6: Small Organ breast, thyroid, testes

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

**Diagnostic Ultrasound Indications for Use Form
P12 Trolley with 2P1 Linear Array Transducer**

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

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Power	Combined (Specify) ^[1]	Other (Specify) ^{[2][3]}
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal	P	P	P		P	P	Note 1	Note 2
	Abdominal								
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify) *								
	Neonatal Cephalic	P	P	P	P	P	P	Note 1	Note 2,3
	Adult Cephalic	P	P	P	P	P	P	Note 1	Note 2,3
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
Cardiac	Cardiac Adult	P	P	P		P	P	Note 1	Note 2,3
	Cardiac Pediatric	P	P	P		P	P	Note 1	Note 2,3
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Urology)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M

Note 1: Other Combined includes: B/M; B/THI; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonics, The feature does not use contrast agents

Note 3: TDI Note 4: 4D

Note 6: Small Organ breast, thyroid, testes

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form P12 Trolley with 5P1 Phase Array Transducer

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

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Power	Combined (Specify) ^[1]	Other (Specify) ^{[2][3]}
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal								
	Abdominal								
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	Note 1	Note 2
	Small Organ (Specify) *								
	Neonatal Cephalic	P	P	P	P	P	P	Note 1	Note 2,3
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
Cardiac	Cardiac Adult	P	P	P	P	P	P	Note 1	Note 2,3
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Urology)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M

Note 1: Other Combined includes: B/M; B/THI; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonics, The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ breast, thyroid, testes

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form P12 Trolley with 6V1 Micro-curved Array Transducer

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

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Power	Combined (Specify) ^[1]	Other (Specify) ^{[2][3]}
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal								
	Abdominal								
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify) *								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal	P	P	P		P	P	Note 1	Note 2
	Trans-vaginal	P	P	P		P	P	Note 1	Note 2
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Urology)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M

Note 1: Other Combined includes: B/M; B/THI; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonics, The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ breast, thyroid, testes

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

**Diagnostic Ultrasound Indications for Use Form
P12 Trolley with 6V3 Micro-curved Array Transducer**

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

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Power	Combined (Specify) ^[1]	Other (Specify) ^{[2][3]}
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal								
	Abdominal								
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify) *								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal	P	P	P		P	P	Note 1	Note 2
	Trans-vaginal	P	P	P		P	P	Note 1	Note 2
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Urology)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M

Note 1: Other Combined includes: B/M; B/THI; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonics, The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ breast, thyroid, testes

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form
P12 Trolley with EC9-5 Micro-curved Array Transducer

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

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Power	Combined (Specify) ^[1]	Other (Specify) ^{[2][3]}
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal								
	Abdominal								
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify) *								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal	P	P	P		P	P	Note 1	Note 2
	Trans-vaginal	P	P	P		P	P	Note 1	Note 2
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Urology)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M

Note 1: Other Combined includes: B/M; B/THI; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonics, The feature does not use contrast agents

Note 3: TDI

Note 4: 3D

Note 5: 4D

Note 6: Small Organ breast, thyroid, testes

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

**Diagnostic Ultrasound Indications for Use Form
P12 Trolley with C611 Micro-curved Array Transducer**

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

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Power	Combined (Specify) ^[1]	Other (Specify) ^{[2][3]}
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal	P	P	P		P	P	Note 1	Note 2
	Abdominal								
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	Note 1	Note 2
	Small Organ (Specify) *								
	Neonatal Cephalic	P	P	P	P	P	P	Note 1	Note 2,3
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric	P	P	P	P	P	P	Note 1	Note 2,3
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Urology)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M

Note 1: Other Combined includes: B/M; B/THI; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonics, The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ breast, thyroid, testes

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

**Diagnostic Ultrasound Indications for Use Form
P12 Trolley with C362 Curved Array Transducer**

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

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Power	Combined (Specify) ^[1]	Other (Specify) ^{[2][3]}
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal	P	P	P		P	P	Note 1	Note 2
	Abdominal	P	P	P		P	P	Note 1	Note 2
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify) *								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)	P	P	P		P	P	Note 1	Note 2
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Urology)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M

Note 1: Other Combined includes: B/M; B/THI; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonics, The feature does not use contrast agents

Note 3: TDI

Note 4: 3D

Note 5: 4D

Note 6: Small Organ breast, thyroid, testes

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

**Diagnostic Ultrasound Indications for Use Form
P12 Trolley with C344 Curved Array Transducer**

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

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Power	Combined (Specify) ^[1]	Other (Specify) ^{[2][3]}
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal	P	P	P		P	P	Note 1	Note 2
	Abdominal	P	P	P		P	P	Note 1	Note 2
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify) *								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)	P	P	P		P	P	Note 1	Note 2
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Urology)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M

Note 1: Other Combined includes: B/M; B/THI; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonics, The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ breast, thyroid, testes

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

**Diagnostic Ultrasound Indications for Use Form
P12 Trolley with C354 Curved Array Transducer**

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

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Power	Combined (Specify) ^[1]	Other (Specify) ^{[2][3]}
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal	N	N	N		N	N	Note 1	Note 2
	Abdominal	N	N	N		N	N	Note 1	Note 2
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify) *								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)	N	N	N		N	N	Note 1	Note 2
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Urology)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M

Note 1: Other Combined includes: B/M; B/THI; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonics, The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ breast, thyroid, testes

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

**Diagnostic Ultrasound Indications for Use Form
P12 Trolley with VC6-2 Curved Array Transducer**

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

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Power	Combined (Specify) ^[1]	Other (Specify) ^{[2][3]}
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal	P	P	P		P	P	Note 1	Note 2,4
	Abdominal	P	P	P		P	P	Note 1	Note 2,4
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify) *								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)	P	P	P		P	P	Note 1	Note 2,4
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Urology)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M

Note 1: Other Combined includes: B/M; B/THI; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonics, The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ breast, thyroid, testes

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form
P12 Trolley with L743 Linear Array Transducer

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

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Power	Combined (Specify) ^[1]	Other (Specify) ^{[2][3]}
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal								
	Abdominal								
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify) *	P	P	P		P	P	Note 1	Note 2
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)	P	P	P		P	P	Note 1	Note 2
	Musculo-skeletal (Superficial)	P	P	P		P	P	Note 1	Note 2
	Intravascular								
	Other (Ob/GYN)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel	P	P	P		P	P	Note 1	Note 2
	Other (Urology)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M

Note 1: Other Combined includes: B/M; B/THI; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonics, The feature does not use contrast agents

Note 3: TDI

Note 4: 3D

Note 5: 4D

Note 6: Small Organ breast, thyroid, testes

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

**Diagnostic Ultrasound Indications for Use Form
P12 Trolley with L741 Linear Array Transducer**

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

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Power	Combined (Specify) ^[1]	Other (Specify) ^{[2][3]}
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal								
	Abdominal								
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify) *	P	P	P		P	P	Note 1	Note 2,5
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)	P	P	P		P	P	Note 1	Note 2
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel	P	P	P		P	P	Note 1	Note 2
	Other (Urology)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M

Note 1: Other Combined includes: B/M; B/THI; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonics, The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ breast, thyroid, testes

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

**Diagnostic Ultrasound Indications for Use Form
P12 Trolley with L742 Linear Array Transducer**

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

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Power	Combined (Specify) ^[1]	Other (Specify) ^{[2][3]}
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal								
	Abdominal								
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify) *	P	P	P		P	P	Note 1	Note 2,5
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)	P	P	P		P	P	Note 1	Note 2
	Musculo-skeletal (Superficial)	P	P	P		P	P	Note 1	Note 2
	Intravascular								
	Other (Ob/GYN)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel	P	P	P		P	P	Note 1	Note 2
	Other (Urology)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M

Note 1: Other Combined includes: B/M; B/THI; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonics, The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ breast, thyroid, testes

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

**Diagnostic Ultrasound Indications for Use Form
P25 Trolley Ultrasonic Diagnostic Imaging System**

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

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Power	Combined (Specify) ^[1]	Other (Specify) ^{[2][3]}
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal	N	N	N		N	N	Note 1	Note 2,4,5
	Abdominal	N	N	N		N	N	Note 1	Note 2,4,5
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric	N	N	N		N	N	Note 1	Note 2,4
	Small Organ (Specify) *	N	N	N		N	N	Note 1	Note 2,4,5
	Neonatal Cephalic	N	N	N	N	N	N	Note 1	Note 2,3,4
	Adult Cephalic	N	N	N	N	N	N	Note 1	Note 2,3,4
	Trans-rectal	N	N	N		N	N	Note 1	Note 2,4
	Trans-vaginal	N	N	N		N	N	Note 1	Note 2,4
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)	N	N	N		N	N	Note 1	Note 2,4
	Musculo-skeletal (Superficial)	N	N	N		N	N	Note 1	Note 2,4
	Intravascular								
	Other (Ob/GYN)	N	N	N		N	N	Note 1	Note 2,4,5
Cardiac	Cardiac Adult	N	N	N	N	N	N	Note 1	Note 2,3,4
	Cardiac Pediatric	N	N	N	N	N	N	Note 1	Note 2,3,4
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	Note 1	Note 2,4
	Other (Urology)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M

Note 1: Other Combined includes: B/M; B/THI; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonics, The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ breast, thyroid, testes

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

**Diagnostic Ultrasound Indications for Use Form
P25 Trolley with 2P1 Phase Array Transducer**

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

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Power	Combined (Specify) ^[1]	Other (Specify) ^{[2][3]}
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal								
	Abdominal	N	N	N		N	N	Note 1	Note 2,4
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify) *								
	Neonatal Cephalic	N	N	N		N	N	Note 1	Note 2,3,4
	Adult Cephalic	N	N	N		N	N	Note 1	Note 2,3,4
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
Cardiac	Cardiac Adult	N	N	N		N	N	Note 1	Note 2,3,4
	Cardiac Pediatric	N	N	N		N	N	Note 1	Note 2,3,4
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Urology)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M

Note 1: Other Combined includes: B/M; B/THI; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonics, The feature does not use contrast agents

Note 3: TDI

Note 4: 3D

Note 5: 4D

Note 6: Small Organ breast, thyroid, testes

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

**Diagnostic Ultrasound Indications for Use Form
P25 Trolley with 5P1 Phase Array Transducer**

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

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Power	Combined (Specify) ^[1]	Other (Specify) ^{[2][3]}
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal								
	Abdominal								
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric	N	N	N		N	N	Note 1	Note 2,4
	Small Organ (Specify) *								
	Neonatal Cephalic	N	N	N	N	N	N	Note 1	Note 2,3,4
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric	N	N	N		N	N	Note 1	Note 2,3,4
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Urology)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M

Note 1: Other Combined includes: B/M; B/THI; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonics, The feature does not use contrast agents

Note 3: TDI

Note 4: 3D

Note 5: 4D

Note 6: Small Organ breast, thyroid, testes

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form
P25 Trolley with 6V1 Micro-curved Array Transducer

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

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Power	Combined (Specify) ^[1]	Other (Specify) ^{[2][3]}
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal								
	Abdominal								
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify) *								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal	N	N	N		N	N	Note 1	Note 2,4
	Trans-vaginal	N	N	N		N	N	Note 1	Note 2,4
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Urology)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M

Note 1: Other Combined includes: B/M; B/THI; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonics, The feature does not use contrast agents

Note 3: TDI

Note 4: 3D

Note 5: 4D

Note 6: Small Organ breast, thyroid, testes

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

**Diagnostic Ultrasound Indications for Use Form
P25 Trolley with 6V3 Micro-curved Array Transducer**

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

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Power	Combined (Specify) ^[1]	Other (Specify) ^{[2][3]}
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal								
	Abdominal								
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify) *								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal	N	N	N		N	N	Note 1	Note 2,4
	Trans-vaginal	N	N	N		N	N	Note 1	Note 2,4
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Urology)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M

Note 1: Other Combined includes: B/M; B/THI; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonics, The feature does not use contrast agents

Note 3: TDI

Note 4: 3D

Note 5: 4D

Note 6: Small Organ breast, thyroid, testes

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form
P25 Trolley with EC9-5 Micro-curved Array Transducer

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

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Power	Combined (Specify) ^[1]	Other (Specify) ^{[2][3]}
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal								
	Abdominal								
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify) *								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal	N	N	N		N	N	Note 1	Note 2,4
	Trans-vaginal	N	N	N		N	N	Note 1	Note 2,4
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Urology)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M

Note 1: Other Combined includes: B/M; B/THI; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonics, The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ breast, thyroid, testes

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form
P25 Trolley with C611 Micro-curved Array Transducer

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

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Power	Combined (Specify) ^[1]	Other (Specify) ^{[2][3]}
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal								
	Abdominal	N	N	N		N	N	Note 1	Note 2,4
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric	N	N	N		N	N	Note 1	Note 2,4
	Small Organ (Specify) *								
	Neonatal Cephalic	N	N	N	N	N	N	Note 1	Note 2,3,4
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric	N	N	N		N	N	Note 1	Note 2,3,4
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Urology)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M

Note 1: Other Combined includes: B/M; B/THI; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonics, The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ breast, thyroid, testes

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

**Diagnostic Ultrasound Indications for Use Form
P25 Trolley with C362 Curved Array Transducer**

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

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Power	Combined (Specify) ^[1]	Other (Specify) ^{[2][3]}
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal	N	N	N		N	N	Note 1	Note 2,4
	Abdominal	N	N	N		N	N	Note 1	Note 2,4
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify) *								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)	N	N	N		N	N	Note 1	Note 2,4
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Urology)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M

Note 1: Other Combined includes: B/M; B/THI; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonics, The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ breast, thyroid, testes

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

**Diagnostic Ultrasound Indications for Use Form
P25 Trolley with C344 Curved Array Transducer**

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

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Power	Combined (Specify) ^[1]	Other (Specify) ^{[2][3]}
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal	N	N	N		N	N	Note 1	Note 2,4
	Abdominal	N	N	N		N	N	Note 1	Note 2,4
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify) *								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)	N	N	N		N	N	Note 1	Note 2,4
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Urology)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M

Note 1: Other Combined includes: B/M; B/THI; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonics, The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ breast, thyroid, testes

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

**Diagnostic Ultrasound Indications for Use Form
P25 Trolley with VC6-2 Curved Array Transducer**

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

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Power	Combined (Specify) ^[1]	Other (Specify) ^{[2][3]}
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal	N	N	N		N	N	Note 1	Note 2,4,5
	Abdominal	N	N	N		N	N	Note 1	Note 2,4,5
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify) *								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)	N	N	N		N	N	Note 1	Note 2,4,5
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Urology)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M

Note 1: Other Combined includes: B/M; B/THI; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonics, The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ breast, thyroid, testes

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

**Diagnostic Ultrasound Indications for Use Form
P25 Trolley with L743 Linear Array Transducer**

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

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Power	Combined (Specify) ^[1]	Other (Specify) ^{[2][3]}
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal								
	Abdominal								
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric	N	N	N		N	N	Note 1	Note 2,4
	Small Organ (Specify) *								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)	N	N	N		N	N	Note 1	Note 2,4
	Musculo-skeletal (Superficial)	N	N	N		N	N	Note 1	Note 2,4
	Intravascular								
	Other (Ob/GYN)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	Note 1	Note 2,4
	Other (Urology)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M

Note 1: Other Combined includes: B/M; B/THI; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonics, The feature does not use contrast agents

Note 3: TDI

Note 4: 3D

Note 5: 4D

Note 6: Small Organ breast, thyroid, testes

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

**Diagnostic Ultrasound Indications for Use Form
P25 Trolley with L741 Linear Array Transducer**

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

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Power	Combined (Specify) ^[1]	Other (Specify) ^{[2][3]}
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal								
	Abdominal								
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify) *	N	N	N		N	N	Note 1	Note 2,4
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)	N	N	N		N	N	Note 1	Note 2,4
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	Note 1	Note 2,4
	Other (Urology)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M

Note 1: Other Combined includes: B/M; B/THI; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonics, The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ breast, thyroid, testes

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

**Diagnostic Ultrasound Indications for Use Form
P25 Trolley with L742 Linear Array Transducer**

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

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Power	Combined (Specify) ^[1]	Other (Specify) ^{[2][3]}
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal								
	Abdominal								
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify) *	N	N	N		N	N	Note 1	Note 2,4
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)	N	N	N		N	N	Note 1	Note 2,4
	Musculo-skeletal (Superficial)	N	N	N		N	N	Note 1	Note 2,4
	Intravascular								
	Other (Ob/GYN)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	Note 1	Note 2,4
	Other (Urology)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M

Note 1: Other Combined includes: B/M; B/THI; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonics, The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ breast, thyroid, testes

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form P25 Expert Ultrasonic Diagnostic Imaging System

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

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Power	Combined (Specify) ^[1]	Other (Specify) ^{[2][3]}
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal	N	N	N		N	N	Note 1	Note 2,4,5
	Abdominal	N	N	N		N	N	Note 1	Note 2,4,5
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric	N	N	N		N	N	Note 1	Note 2,4
	Small Organ (Specify) *	N	N	N		N	N	Note 1	Note 2,4,6
	Neonatal Cephalic	N	N	N	N	N	N	Note 1	Note 2,3,4
	Adult Cephalic	N	N	N	N	N	N	Note 1	Note 2,3,4
	Trans-rectal	N	N	N		N	N	Note 1	Note 2,4
	Trans-vaginal	N	N	N		N	N	Note 1	Note 2,4
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)	N	N	N		N	N	Note 1	Note 2,4
	Musculo-skeletal (Superficial)	N	N	N		N	N	Note 1	Note 2,4
	Intravascular								
	Other (Ob/GYN)	N	N	N		N	N	Note 1	Note 2,4,5
	Other (Urology)	N	N	N		N	N	Note 1	Notes 2, 4
Cardiac	Cardiac Adult	N	N	N	N	N	N	Note 1	Note 2,3,4
	Cardiac Pediatric	N	N	N	N	N	N	Note 1	Note 2,3,4
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)	N	N	N	N	N	N	Note 1	Note 2,3,4
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	Note 1	Note 2,4
	Other (Urology)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M

Note 1: Other Combined includes: B/M; B/THI; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonics, The feature does not use contrast agents

Note 3: TDI

Note 4: 3D

Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form
P25 Expert with 2P1 Phase Array Transducer

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

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Power	Combined (Specify) ^[1]	Other (Specify) ^{[2][3]}
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal								
	Abdominal	P	P	P		P	P	Note 1	Notes 2, 4
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify) *								
	Neonatal Cephalic	P	P	P	P	P	P	Note 1	Notes 2,3,4
	Adult Cephalic	P	P	P	P	P	P	Note 1	Notes 2,3,4
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
	Other(Urology)								
Cardiac	Cardiac Adult	P	P	P	P	P	P	Note 1	Notes 2,3,4
	Cardiac Pediatric	P	P	P	P	P	P	Note 1	Notes 2,3,4
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Urology)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M

Note 1: Other Combined includes: B/M; B/THI; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonics, The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ breast, thyroid, testes

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form
P25 Expert with 5P1 Phase Array Transducer

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

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Power	Combined (Specify) ^[1]	Other (Specify) ^{[2][3]}
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal								
	Abdominal								
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	Note 1	Notes 2,4
	Small Organ (Specify) *								
	Neonatal Cephalic	P	P	P	P	P	P	Note 1	Notes 2,3,4
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
	Other(Urology)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric	P	P	P	P	P	P	Note 1	Notes 2,3,4
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Urology)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M

Note 1: Other Combined includes: B/M; B/THI; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonics, The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ breast, thyroid, testes

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form
P25 Expert with C613 Micro-curved Array Transducer

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

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Power	Combined (Specify) ^[1]	Other (Specify) ^{[2][3]}
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal								
	Abdominal	P	P	P		P	P	Note 1	Notes 2,4
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	Note 1	Notes 2,4
	Small Organ (Specify) *								
	Neonatal Cephalic	P	P	P	P	P	P	Note 1	Notes 2,3,4
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
	Other (Urology)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric	P	P	P	P	P	P	Note 1	Notes 2,3,4
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Urology)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M

Note 1: Other Combined includes: B/M; B/THI; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonics, The feature does not use contrast agents

Note 3: TDI

Note 4: 3D

Note 5: 4D

Note 6: Small Organ breast, thyroid, testes

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form
P25 Expert with 6V1 Micro-Curved Array Transducer

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

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Power	Combined (Specify) ^[1]	Other (Specify) ^{[2][3]}
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal								
	Abdominal								
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify) *								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal	P	P	P		P	P	Note 1	Notes 2,4
	Trans-vaginal	P	P	P		P	P	Note 1	Notes 2,4
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
	Other (Urology)	P	P	P		P	P	Note 1	Notes 2,4
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Urology)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M

Note 1: Other Combined includes: B/M; B/THI; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonics, The feature does not use contrast agents

Note 3: TDI

Note 4: 3D

Note 5: 4D

Note 6: Small Organ breast, thyroid, testes

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form
P25 Expert with 6V3 Micro-Curved Array Transducer

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

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Power	Combined (Specify) ^[1]	Other (Specify) ^{[2][3]}
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal								
	Abdominal								
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify) *								
	Neonatal Cephalic								
	Adult Cephalic	P	P	P		P	P	Note 1	Notes 2,4
	Trans-rectal	P	P	P		P	P	Note 1	Notes 2,4
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
	Other (Urology)	P	P	P		P	P	Note 1	Notes 2,4
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Urology)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M

Note 1: Other Combined includes: B/M; B/THI; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonics, The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ breast, thyroid, testes

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form
P25 Expert with EC9-5 Micro-Curved Array Transducer

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

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Power	Combined (Specify) ^[1]	Other (Specify) ^{[2][3]}
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal								
	Abdominal								
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify) *								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal	N	N	N		N	N	Note 1	Notes 2,4
	Trans-vaginal	N	N	N		N	N	Note 1	Notes 2,4
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
	Other (Urology)	N	N	N		N	N	Note 1	Notes 2,4
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Urology)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M

Note 1: Other Combined includes: B/M; B/THI; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonics, The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ breast, thyroid, testes

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form
P25 Expert with BCC9-5 Micro-Curved Array Transducer

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

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Power	Combined (Specify) ^[1]	Other (Specify) ^{[2][3]}
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal								
	Abdominal								
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify) *								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal	N	N	N		N	N	Note 1	Notes 2,4
	Trans-vaginal	N	N	N		N	N	Note 1	Notes 2,4
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
	Other (Urology)	N	N	N		N	N	Note 1	Notes 2,4
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Urology)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M

Note 1: Other Combined includes: B/M; B/THI; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonics, The feature does not use contrast agents

Note 3: TDI

Note 4: 3D

Note 5: 4D

Note 6: Small Organ breast, thyroid, testes

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form
P25 Expert with BCL 10-5 Biplane Array Transducer

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

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Power	Combined (Specify) ^[1]	Other (Specify) ^{[2][3]}
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal								
	Abdominal								
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify) *								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal	N	N	N		N	N	Note 1	Notes 2,4
	Trans-vaginal	N	N	N		N	N	Note 1	Notes 2,4
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
	Other (Urology)	N	N	N		N	N	Note 1	Notes 2,4
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Urology)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M

Note 1: Other Combined includes: B/M; B/THI; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonics, The feature does not use contrast agents

Note 3: TDI

Note 4: 3D

Note 5: 4D

Note 6: Small Organ breast, thyroid, testes

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form P25 Expert with C344 Curved Array Transducer

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

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Power	Combined (Specify) ^[1]	Other (Specify) ^{[2][3]}
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal	P	P	P		P	P	Note 1	Note 2,4
	Abdominal	P	P	P		P	P	Note 1	Note 2,4
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify) *								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)	P	P	P		P	P	Note 1	Note 2,4
	Other (Urology)	P	P	P		P	P	Note 1	Note 2,4
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Urology)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M

Note 1: Other Combined includes: B/M; B/THI; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonics, The feature does not use contrast agents

Note 3: TDI

Note 4: 3D

Note 5: 4D

Note 6: Small Organ breast, thyroid, testes

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form
P25 Expert with C353 Curved Array Transducer

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

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Power	Combined (Specify) ^[1]	Other (Specify) ^{[2][3]}
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal	N	N	N		N	N	Note 1	Notes 2,4
	Abdominal	N	N	N		N	N	Note 1	Notes 2,4
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify) *								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)	N	N	N		N	N	Note 1	Notes 2,4
	Other (Urology)	N	N	N		N	N	Note 1	Notes 2,4
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Urology)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M

Note 1: Other Combined includes: B/M; B/THI; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonics, The feature does not use contrast agents

Note 3: TDI

Note 4: 3D

Note 5: 4D

Note 6: Small Organ breast, thyroid, testes

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form
P25 Expert with C542 Curved Array Transducer

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

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Power	Combined (Specify) ^[1]	Other (Specify) ^{[2][3]}
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal								
	Abdominal	N	N	N		N	N	Note 1	Notes 2,4
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric	N	N	N		N	N	Note 1	Notes 2,4
	Small Organ (Specify) *								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
	Other (Urology)	N	N	N		N	N	Note 1	Notes 2,4
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Urology)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M

Note 1: Other Combined includes: B/M; B/THI; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonics, The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ breast, thyroid, testes

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form
P25 Expert with C354 Curved Array Transducer

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

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Power	Combined (Specify) ^[1]	Other (Specify) ^{[2][3]}
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal	P	P	P		P	P	Note 1	Note 2,4
	Abdominal	P	P	P		P	P	Note 1	Note 2,4
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify) *								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)	P	P	P		P	P	Note 1	Note 2,4
	Other (Urology)	P	P	P		P	P	Note 1	Note 2,4
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Urology)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M

Note 1: Other Combined includes: B/M; B/THI; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonics, The feature does not use contrast agents

Note 3: TDI

Note 4: 3D

Note 5: 4D

Note 6: Small Organ breast, thyroid, testes

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form
P25 Expert with C322 Curved Array Transducer

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

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Power	Combined (Specify) ^[1]	Other (Specify) ^{[2][3]}
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal	N	N	N		N	N	Note 1	Notes 2,4
	Abdominal	N	N	N		N	N	Note 1	Notes 2,4
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify) *								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)	N	N	N		N	N	Note 1	Notes 2,4
	Other (Urology)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Urology)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M

Note 1: Other Combined includes: B/M; B/THI; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonics, The feature does not use contrast agents

Note 3: TDI

Note 4: 3D

Note 5: 4D

Note 6: Small Organ breast, thyroid, testes

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form
P25 Expert with VC6-2 Curved Array Transducer

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

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Power	Combined (Specify) ^[1]	Other (Specify) ^{[2][3]}
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal	P	P	P		P	P	Note 1	Notes 2,4,5
	Abdominal	P	P	P		P	P	Note 1	Notes 2,4,5
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify) *								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)	P	P	P		P	P	Note 1	Notes 2,4,5
	Other (Urology)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Urology)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M

Note 1: Other Combined includes: B/M; B/THI; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonics, The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ breast, thyroid, testes

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

**Diagnostic Ultrasound Indications for Use Form
P25 Expert with L741 Linear Array Transducer**

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

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Power	Combined (Specify) ^[1]	Other (Specify) ^{[2][3]}
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal								
	Abdominal								
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify) *	P	P	P		P	P	Note 1	Notes 2,4,6
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)	P	P	P	P	P	P	Note 1	Notes 2,4
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
	Other (Urology)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel	P	P	P		P	P	Note 1	Notes 2,4
	Other (Urology)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M

Note 1: Other Combined includes: B/M; B/THI; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonics, The feature does not use contrast agents

Note 3: TDI

Note 4: 3D

Note 5: 4D

Note 6: Small Organ breast, thyroid, testes

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form P25 Expert with L742 Linear Array Transducer

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

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Power	Combined (Specify) ^[1]	Other (Specify) ^{[2][3]}
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal								
	Abdominal								
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify) *	P	P	P		P	P	Note 1	Notes 2,4,6
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)	P	P	P		P	P	Note 1	Notes 2,4
	Musculo-skeletal (Superficial)	P	P	P		P	P	Note 1	Notes 2,4
	Intravascular								
	Other (Ob/GYN)								
	Other (Urology)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel	P	P	P		P	P	Note 1	Notes 2,4
	Other (Urology)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M

Note 1: Other Combined includes: B/M; B/THI; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonics, The feature does not use contrast agents

Note 3: TDI

Note 4: 3D

Note 5: 4D

Note 6: Small Organ breast, thyroid, testes

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form P25 Expert with L752 Linear Array Transducer

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

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Power	Combined (Specify) ^[1]	Other (Specify) ^{[2][3]}
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal								
	Abdominal								
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify) *	N	N	N		N	N	Note 1	Notes 2,4,6
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)	N	N	N		N	N	Note 1	Notes 2,4
	Musculo-skeletal (Superficial)	N	N	N		N	N	Note 1	Notes 2,4
	Intravascular								
	Other (Ob/GYN)								
	Other (Urology)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	Note 1	Notes 2,4
	Other (Urology)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M

Note 1: Other Combined includes: B/M; B/THI; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonics, The feature does not use contrast agents

Note 3: TDI

Note 4: 3D

Note 5: 4D

Note 6: Small Organ breast, thyroid, testes

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form
P25 Expert with 10L-1 Linear Array Transducer

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

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Power	Combined (Specify) ^[1]	Other (Specify) ^{[2][3]}
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal								
	Abdominal								
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify) *	N	N	N		N	N	Note 1	Notes 2,4,6
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)	N	N	N		N	N	Note 1	Notes 2,4
	Musculo-skeletal (Superficial)	N	N	N		N	N	Note 1	Notes 2,4
	Intravascular								
	Other (Ob/GYN)								
	Other (Urology)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	Note 1	Notes 2,4
	Other (Urology)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M

Note 1: Other Combined includes: B/M; B/THI; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonics, The feature does not use contrast agents

Note 3: TDI

Note 4: 3D

Note 5: 4D

Note 6: Small Organ breast, thyroid, testes

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form
P25 Expert with MPTEE Multi-Plane Array Transducer

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

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Power	Combined (Specify) ^[1]	Other (Specify) ^{[2][3]}
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal								
	Abdominal								
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify) *								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
	Other (Urology)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)	P	P	P		P	P	Note 1	Notes 2,3,4
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Urology)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M

Note 1: Other Combined includes: B/M; B/THI; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonics, The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ breast, thyroid, testes

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form
P25 Expert with MPTEE mini Multi-Plane Array Transducer

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

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Power	Combined (Specify) ^[1]	Other (Specify) ^{[2][3]}
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal								
	Abdominal								
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify) *								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
	Other (Urology)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)	P	P	P		P	P	Note 1	Notes 2,3,4
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Urology)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M

Note 1: Other Combined includes: B/M; B/THI; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonics, The feature does not use contrast agents

Note 3: TDI

Note 4: 3D

Note 5: 4D

Note 6: Small Organ breast, thyroid, testes

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

**Diagnostic Ultrasound Indications for Use Form
P12 Expert Ultrasonic Diagnostic Imaging System**

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

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	Specific (Tracks 1&3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other * (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal	P	P	P		P	P	Note 1	Note 2,4,5
	Abdominal	P	P	P		P	P	Note 1	Note 2,4,5
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	Note 1	Note 2,4
	Small Organ (Specify)	P	P	P		P	P	Note 1	Note
	Neonatal Cephalic	P	P	P	P	P	P	Note 1	Note 2,3,4
	Adult Cephalic	P	P	P	P	P	P	Note 1	Note 2,3,4
	Trans-rectal	P	P	P		P	P	Note 1	Note 2,4
	Trans-vaginal	P	P	P		P	P	Note 1	Note 2,4
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)	P	P	P		P	P	Note 1	Note 2,4
	Musculo-skeletal (Superficial)	P	P	P		P	P	Note 1	Note 2,4
	Other (Ob/GYN)	P	P	P		P	P	Note 1	Note 2,4,5
	Other (Urology)	P	P	P		P	P	Note 1	Note 2,4,
Cardiac	Cardiac Adult	P	P	P	P	P	P	Note 1	Note 2,3,4
	Cardiac Pediatric	P	P	P	P	P	P	Note 1	Note 2,3,4
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel	P	P	P		P	P	Note 1	Note 2,4
	Other (Urology)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: Other Combined includes: B/M; B/PWD; B/THI; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes Note 7: Elastography

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form

P12 Expert with Transducer: C322 CURVE ARRAY

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

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	Specific (TRACKS 1&3)	B	M	PW	CWD	Color Doppler	Power (Amplitude) Doppler	Other * Combined	Other * (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal	P	P	P		P	P	Note 1	Notes 2,4
	Abdominal	P	P	P		P	P	Note 1	Notes 2,4
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)	P	P	P		P	P	Note 1	Note 2,4
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Urology)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging, The feature does not use contrast agents

Note 3: TDI

Note 4: 3D

Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes Note 7: Elastography

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form

P12 Expert with Diagnostic Ultrasound Transducer: C344 Curve Array

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

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	Specific (Tracks 1&3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal	P	P	P		P	P	Note 1	Notes 2,4
	Abdominal	P	P	P		P	P	Note 1	Notes 2,4
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)	P	P	P		P	P	Note 1	Notes 2,4
	Cardiac	Cardiac Adult							
Cardiac Pediatric									
Intravascular (Cardiac)									
Trans-esoph. (Cardiac)									
Intra-cardiac									
Other (Specify)									
Peripheral Vessel	Peripheral vessel								
	Other (Urology)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M;B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic, The feature does not use contrast agents

Note 3: TDI

Note 4: 3D

Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes Note 7: Elastography

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form

P12 Expert with Diagnostic Ultrasound Transducer: C354 Curve Array

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

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	Specific (Tracks 1&3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other * Combined	Other * (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal	P	P	P		P	P	Note 1	Notes 2,4
	Abdominal	P	P	P		P	P	Note 1	Notes 2,4
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)	P	P	P		P	P	Note 1	Notes 2,4
	Cardiac	Cardiac Adult							
Cardiac Pediatric									
Intravascular (Cardiac)									
Trans-esoph. (Cardiac)									
Intra-cardiac									
Other (Specify)									
Peripheral Vessel	Peripheral vessel								
	Other (Urology)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ breast, thyroid, testes Note 7: Elastography

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form

P12 Expert with Diagnostic Ultrasound Transducer: C542 Curve Array

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

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	Specific (Tracks 1&3)	B	M	PW D	CWD	Color Doppler	Power (Amplitude) Doppler	Other * Combined	Other * (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal								
	Abdominal	P	P	P		P	P	Note 1	Notes 2,4
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	Note 1	Notes 2,4
	Small Organ (Specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Urology)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ breast, thyroid, testes Note 7: Elastography

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form
P12 Expert with Diagnostic Ultrasound Transducer: 3C-A Curve Array

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

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	Specific (Tracks 1&3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal	E	E	E		E	E	Note 1	Notes 2,4
	Abdominal	E	E	E		E	E	Note 1	Notes 2,4
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)	E	E	E		E	E	Note 1	Notes 2,4
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Urology)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ breast, thyroid, testes Note 7: Elastography

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form

P12 Expert with Diagnostic Ultrasound Transducer: VC6-2 Curved Array

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

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	Specific (Tracks 1&3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other * Combined	Other* (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal	P	P	P		P	P	Note 1	Notes
	Abdominal	P	P	P		P	P	Note 1	Notes
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vagina								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)	P	P	P		P	P	Note 1	Notes
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Urology)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ breast, thyroid, testes Note 7: Elastography

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form

P12 Expert with Diagnostic Ultrasound Transducer: C613 Micro-Curve Array

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

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	Specific (Tracks 1&3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other * Combined	Other * (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal								
	Abdominal	P	P	P		P	P	Note 1	Notes 2,4
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	Note 1	Notes 2,4
	Small Organ (Specify)								
	Neonatal Cephalic	P	P	P	P	P	P	Note 1	Notes 2,3,4
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric	P	P	P		P	P	Note 1	Notes 2,3,4
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Urology)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ breast, thyroid, testes Note 7: Elastography

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form
P12 Expert with Diagnostic Ultrasound Transducer: 2P1 Phase Array

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

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	Specific (Tracks 1&3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other *	Other *
								Combined	(Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal								
	Abdominal	P	P	P		P	P	Note 1	Notes 2,4
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify)								
	Neonatal Cephalic	P	P	P	P	P	P	Note 1	Note 2,3,4
	Adult Cephalic	P	P	P	P	P	P	Note 1	Note 2,3,4
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
Cardiac	Cardiac Adult	P	P	P	P	P	P	Note 1	Note 2,3,4
	Cardiac Pediatric	P	P	P	P	P	P	Note 1	Note 2,3,4
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Urology)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ breast, thyroid, testes Note 7: Elastography

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form
P12 Expert with Diagnostic Ultrasound Transducer: 5P1 Phase Array

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

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	Specific (Tracks 1&3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other * Combined	Other * (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal								
	Abdominal								
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	Note 1	Notes 2,4
	Small Organ (Specify)								
	Neonatal Cephalic	P	P	P	P	P	P	Note 1	Notes
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric	P	P	P	P	P	P	Note 1	Notes
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Urology)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ breast, thyroid, testes Note 7: Elastography

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form
P12 Expert with Diagnostic Ultrasound Transducer: 4P-A Phase Array

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

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	Specific (Tracks 1&3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other *	Other *
								Combined	(Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal								
	Abdominal								
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify)								
	Neonatal Cephalic	E	E	E	E	E	E	Note 1	Notes
	Adult Cephalic	E	E	E	E	E	E	Note 1	Notes
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
Cardiac	Cardiac Adult	E	E	E	E	E	E	Note 1	Notes
	Cardiac Pediatric	E	E	E	E	E	E	Note 1	Notes
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Urology)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents

Note 3: TDI

Note 4: 3D

Note 5: 4D

Note 6: Small Organ breast, thyroid, testes

Note 7: Elastography

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications form Use Form
P12 Expert with Diagnostic Ultrasound Transducer: L741 Linear Array

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

Clinical Application		Mode of Operation							
General (TRACK 1 only)	Specific (Tracks 1&3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other * Combined	Other * (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal								
	Abdominal								
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify)	P	P	P		P	P	Note 1	Notes
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)	P	P	P		P	P	Note 1	Notes 2,4
	Musculo-skeletal (Superficial)	P	P	P		P	P	Note 1	Notes 2,4
	Intravascular								
	Other (Ob/GYN)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel	P	P	P		P	P	Note 1	Notes 2,4
	Other (Urology)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4

Note 6: Small Organ breast, thyroid, testes Note 7: Elastography

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form

P12 Expert with Diagnostic Ultrasound Transducer: L742 Linear Array

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

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other *	Other * (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal								
	Abdominal								
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify)	P	P	P		P	P	Note 1	Notes 2,4,6
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)	P	P	P		P	P	Note 1	Notes 2,4
	Musculo-skeletal (Superficial)	P	P	P		P	P	Note 1	Notes 2,4
	Intravascular								
	Other (Ob/GYN)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel	P	P	P		P	P	Note 1	Notes 2,4
	Other (Urology)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ breast, thyroid, testes Note 7: Elastography

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form
P12 Expert with Diagnostic Ultrasound Transducer: 10L1 Linear Array

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

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	Specific (Tracks 1&3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other * Combined	Other * Specify
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal								
	Abdominal								
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify)	P	P	P		P	P	Note 1	Notes
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)	P	P	P		P	P	Note 1	Notes 2,4
	Musculo-skeletal (Superficial)	P	P	P		P	P	Note 1	Notes 2,4
	Intravascular								
	Other (Ob/GYN)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel	P	P	P		P	P	Note 1	Notes 2,4
	Other (Urology)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ breast, thyroid, testes Note 7: Elastography

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form

P12 Expert with Diagnostic Ultrasound Transducer: 10I2 Linear Array

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

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	Specific (Tracks 1&3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other * Combined	Other * Specify
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal								
	Abdominal								
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify)	E	E	E		E	E	Note 1	Notes 2,4,6
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)	E	E	E		E	E	Note 1	Notes 2,4
	Musculo-skeletal (Superficial)	E	E	E		E	E	Note 1	Notes 2,4
	Intravascular								
	Other (Ob/GYN)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel	E	E	E		E	E	Note 1	Notes 2,4
	Other (Urology)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ breast, thyroid, testes Note 7: Elastography

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form
P12 Expert with Diagnostic Ultrasound Transducer: 6V1 Micro-Curved Array

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

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	Specific (Tracks 1&3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other * Combined	Other * (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal								
	Abdominal								
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal	P	P	P		P	P	Note 1	Notes 2,4
	Trans-vaginal	P	P	P		P	P	Note 1	Notes 2,4
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)								
	Musculo-skeletal (Superficial)								
	Other (Ob/GYN)								
Other (Urology)	P	P	P		P	P	Note 1	Notes 2,4	
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Urology)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ breast, thyroid, testes Note 7: Elastography

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form

P12 Expert with Diagnostic Ultrasound Transducer: EC9-5 Micro-Curved Array

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

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	Specific (Tracks 1&3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude)	Other * Combined	Other * Specify
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal								
	Abdominal								
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal	P	P	P		P	P	Note 1	Notes 2,4
	Trans-vaginal	P	P	P		P	P	Note 1	Notes 2,4
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Urology)	P	P	P		P	P	Note 1	Notes 2,4
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Urology)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents

Note 3: TDI

Note 4: 3D

Note 5: 4D

Note 6: Small Organ breast, thyroid, testes Note 7: Elastography

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form

P12 Expert with Diagnostic Ultrasound Transducer: BCC9-5 Micro-Curved Array

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

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	Specific (Tracks 1&3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other * Combined	Other * (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal								
	Abdominal								
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal	P	P	P		P	P	Note 1	Notes 2,4
	Trans-vaginal	P	P	P		P	P	Note 1	Notes 2,4
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
Other (Urology)	P	P	P		P	P	Note 1	Notes 2,4	
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Urology)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents

Note 3: TDI

Note 4: 3D

Note 5: 4D

Note 6: Small Organ breast, thyroid, testes Note 7: Elastography

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form

P12 Expert with Diagnostic Ultrasound Transducer: BCL10-5 Biplane Array

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

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	Specific (Tracks 1&3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other *	Other *
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal								
	Abdominal								
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal	P	P	P		P	P	Note 1	Notes 2,4
	Trans-vaginal	P	P	P		P	P	Note 1	Notes 2,4
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Urology)	P	P	P		P	P	Note 1	Notes 2,4
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Urology)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ breast, thyroid, testes Note 7: Elastography

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510K SUMMARY

MEDISONO Ultrasonic Diagnostic Imaging System

SUBMITTER MEDISONO, LLC
3511 SILVERSIDE RD STE 105
WILMINGTON, de 19810
Phone: 7864165587
Fax: 7864165587

US AGENT JORGE MILLAN, PHD
Official Correspondent for MEDISONO, LLC
601 WEST 20 St., HIALEAH, FL 33010
Email: sigmabiomedical@gmail.com
Web: <https://www.sigmabiomedical.com>

DEVICE NAME AND CLASSIFICATION

TRADE NAME: Medisono Color Doppler Ultrasound System, models P11 Portable, P11 EXPERT Portable, P12 Trolley, P12 Expert, P25 Trolley, and P25 Expert Trolley.

CLASSIFICATION NAME: 892.1550 System, Imaging, Pulsed Doppler, Ultrasonic
Product Code: IYN
892.1560 Ultrasonic, Pulsed Echo, Imaging
Product Code: IYO
892.1570 Transducer, Ultrasonic, Diagnostic
Product Code: ITX

REGULATORY CLASS: Class II
PANEL IDENTIFICATION Radiology

DEVICE DESCRIPTION

The **P11 Portable Color Doppler Ultrasound System** is an integrated preprogrammed color ultrasound imaging system, capable of producing high detail resolution intended for clinical diagnostic imaging applications. The all-digital architecture with progressive dynamic receive focusing allows the system to maximize the utility of all imaging transducers to enhance the diagnostic utility and confidence provided **by** the system. The exam dependent default setting allows the user to have minimum adjustment for imaging the patient, while the in-depth soft-menu control allows the advanced user to set the system for different situations. The architecture allows cost-effective system integration to a variety of upgrade-able options and features. The P1 Portable Diagnostic Ultrasound system is a general purpose, software controlled, diagnostic ultrasound system. Its basic

function is to acquire ultrasound data and display the image in B-Mode (including Tissue Harmonic Image), M-Mode, TDI, Color-Flow Doppler, Pulsed Doppler and Power Doppler, or a combination of these modes, 3D/4D.

The **P11 EXPERT Portable Color Doppler Ultrasound System** is an integrated preprogrammed color ultrasound imaging system, capable of producing high detail resolution intended for clinical diagnostic imaging applications. The all-digital architecture with progressive dynamic receive focusing allows the system to maximize the utility of all imaging transducers to enhance the diagnostic utility and confidence provided by the system. The exam dependent default setting allows the user to have minimum adjustment for imaging the patient, while the in-depth soft-menu control allows the advanced user to set the system for different situations. The architecture allows cost-effective system integration to a variety of upgrade-able options and features. This P11 Expert Portable system is a general purpose, software controlled, diagnostic ultrasound system. Its basic function is to acquire ultrasound data and display the image in B-Mode (including Tissue Harmonic Image), M-Mode, TDI Color-Flow Doppler, Pulsed Doppler and Power Doppler, or a combination of these modes, 3D/4D.

The **P12 Trolley Color Doppler Ultrasound System** is an integrated preprogrammed color ultrasound imaging system, capable of producing high detail resolution intended for clinical diagnostic imaging applications. The all-digital architecture with progressive dynamic receive focusing allows the system to maximize the utility of all imaging transducers to enhance the diagnostic utility and confidence provided by the system. The exam dependent default setting allows the user to have minimum adjustment for imaging the patient, while the in-depth soft-menu control allows the advanced user to set the system for different situations. The architecture allows cost-effective system integration to a variety of upgrade-able options and features. The P12 Trolley Digital Color Doppler Ultrasound System is a general purpose, software controlled, diagnostic ultrasound system. Its basic function is to acquire ultrasound data and display the image in B-Mode (including Tissue Harmonic Image), M-Mode, TDI Color-Flow Doppler, Pulsed Doppler and Power Doppler, or a combination of these modes, 4D.

The **P12 Expert Digital Color Doppler Ultrasound System** is an integrated preprogrammed color ultrasound imaging system, capable of producing high detail resolution intended for clinical diagnostic imaging applications. The basic principle is that system transmits ultrasonic energy into patient body and implements post processing of received echoes to generate onscreen display of anatomic structures and fluid flow within the body. This system is a Track 3 device that employs a wide array of probes that include linear array, convex array and phased array with a frequency range of 1.0 MHz to 15.0 MHz

This system consists of a mobile console with keyboard control panel, power supply module, color LCD monitor and optional probes. The system is a mobile, general purpose, software controlled, color diagnostic ultrasound system. Its basic function is to acquire ultrasound data and to display the image in B-Mode (including Tissue Harmonic Image), M-Mode, TDI, Color-Flow Doppler, Pulsed Wave Doppler, Continued Wave Doppler and Power Doppler, or the combination of these modes, Elastography, 3D/4D.

The **P25 Trolley Color Doppler Ultrasound System** is an integrated preprogrammed color ultrasound imaging system, capable of producing high detail resolution intended for clinical diagnostic imaging applications. The all-digital architecture with progressive dynamic receive focusing allows the system to maximize the utility of all imaging transducers to enhance the diagnostic utility and confidence provided by the system. The exam dependent default setting allows the user to have minimum adjustment for imaging the patient, while the in-depth soft-menu control allows the advanced user to set the system for different situations. The architecture allows cost-effective system integration to a variety of upgrade-able options and features. This system is a general purpose, software controlled, diagnostic ultrasound system. Its basic function is to acquire ultrasound data and display the image in B-Mode (including Tissue Harmonic Image), M-Mode, TDI, Color-Flow Doppler, Pulsed Doppler and Power Doppler, or a combination of these modes, 3D/4D.

The **P25 Expert Color Doppler Ultrasound System** is an integrated preprogrammed color ultrasound imaging system, capable of producing high detail resolution intended for clinical diagnostic imaging applications. The basic principle is that system transmits ultrasonic energy into patient body and implements post processing of received echoes to generate onscreen display of anatomic structures and fluid flow within the body. This system is a Track 3 device that employs a wide array of probes that include linear array, convex array and phased array with a frequency range of 2.0 MHz to 15.0 MHz. This system consists of a mobile console with keyboard control panel, power supply module, color LCD monitor and optional probes. This system is a mobile, general purpose, software controlled, color diagnostic ultrasound system. Its basic function is to acquire ultrasound data and to display the image in B-Mode (including Tissue Harmonic Image), M-Mode, TDI, Color-Flow Doppler, Pulsed Wave Doppler, Continued Wave Doppler and Power Doppler, or the combination of these modes, Elastography, 3D/4D.

Predicate Devices: The proposed system models are substantially equivalent to diagnostic ultrasound systems cleared for marketing in the US. The MEDISONO model P111 Portable is equivalent to the Sonoscape S6 ultrasound system (K112602); the P11 Expert model is

equivalent to the Sonoscape S8 Exp Portable Digital Color Doppler Ultrasound System (K132768); the P12 Trolley model is equivalent to the Sonoscape S11 Digital Color Doppler Ultrasound System (K130801); The P12 Expert model is equivalent to the Sonoscape S12 Digital Color Doppler Ultrasound System (K152396); the P25 Trolley model is equivalent to the Sonoscape S20 Digital Color Doppler Ultrasound System (K110510); and the P25 Expert model is equivalent to the Sonoscape S22 ultrasound system (K142815). All diagnostic ultrasound systems and transducers are manufactured by SONOSCAPE.

Indications for Use: The Medisono Color Doppler Ultrasound System, models P11 Portable, P11 EXPERT Portable, P12 Trolley, P12 Expert, P25 Trolley, and P25 Expert Trolley are general purpose ultrasonic imaging instruments intended for use by a qualified physician for evaluation of Fetal, Abdominal, Pediatric, Small Organ (breast, testes, thyroid), Cephalic (neonatal and adult), Trans-rectal, Trans-vaginal, Peripheral Vascular, Musculo-skeletal (Conventional and Superficial), Cardiac (neonatal and adult), OB/Gyn and Urology.

EFFECTIVENESS AND SAFETY CONSIDERATIONS

Clinical Test:

Clinical testing is not required.

Non-clinical Test:

The Medisono Color Doppler Ultrasound System with added transducer incorporates the same fundamental technology as the predicate device. The device has been tested as Track 3 Device per the FDA Guidance document 'Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers' issued September 9, 2008. The acoustic output is measured and calculated per NEMA UID 2: 2004 Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment and NEMA UD3: 2004 Standards for Real-time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment. The device conforms to applicable medical device safety standards, such as IEC 60601-1:2012 A(2), IEC 60601-1-1, IEC 60601-1-2:2007, IEC 60601-2-37:2007, ISO10993-5:2009 and ISO 10993-10:2010.

COMPARISON TO PREDICATE DEVICE

The subject device has similar technology characteristics and has the same intended use, same design principle, same electrical classification and same accuracy. There are no differences between the devices that affect the usage, safety and effectiveness, thus no new question is raised regarding the safety and effectiveness.

Substantially Equivalent Determination

The evaluation of the MEDISONO Color Doppler Ultrasound system does not raise any additional concerns regarding safety and effectiveness and may therefore be considered substantially equivalent to the predicate devices.