MAY 2 3 2014

K140067

GE Healthcare

510(k) Premarket Notification Submission

**510(k) Summary**

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

| | |
|---|---|
| Date: | April 22, 2014 |
| Submitter: | GE Healthcare<br>9900 Innovation Dr<br>Wauwatosa, WI 53226 |
| Primary Contact Person: | Bryan Behn<br>Regulatory Affairs Manager<br>GE Healthcare<br>T:(414)721-4214<br>F:(414)918-8275 |
| Secondary Contact Person: | Jiawei ZHANG<br>Regulatory Affairs<br>GE Healthcare<br>T: +86 510 8527 8259<br>F: +86 510 8522 7347 |
| Device: Trade Name: | Vivid T8, Vivid T8 Pro |
| Common/Usual Name: | Vivid T8, Vivid T8 Pro |
| Classification Names: | Class II |
| Product Code: | Ultrasonic Pulsed Doppler Imaging System. 21CFR 892.1550 90-IYN Ultrasonic Pulsed Echo Imaging System, 21CFR 892.1560, 90-IYO Diagnostic Ultrasound Transducer, 21 CFR 892.1570, 90-ITX |
| Predicate Device(s): | K121063 GE Vivid S6/S5 BT12<br>K133034 GE LOGIQ F Series |
| Device Description: | The Vivid T8/Vivid T8 Pro is the full featured general purpose diagnostic ultrasound system which consists of a mobile console that provides digital acquisition, processing and display capability. The user interface includes a computer keyboard, color LCD image display and touch panel |
| Intended Use: | Vivid T8/Vivid T8 Pro is Multipurpose Cardiovascular System designed for cardiac and Shared Service Imaging, the system supports following applications: Fetal/OB, Abdominal, Pediatric, Small Organ, Cardiac, Peripheral Vascular, Musculoskeletal Superficial/Conventional, Adult Cephalic, Neonatal Cephalic, Transcranial, Transrectal, Transvaginal and Transesophageal |

Technology: Vivid T8/Vivid T8 Pro employs the same fundamental scientific technology as its predicate devices.

Determination of Substantial Equivalence: Comparison to Predicate Devices

The Vivid T8 and T8 Pro systems are substantially equivalent to the predicate devices with regard to intended use, imaging capabilities, technological characteristics and safety and effectiveness.

| | **Proposed Device Vivid T8/Vivid T8 Pro** | **Predicate Device Vivid S5/S6 (K121063)** |
|---|---|---|
| Indications and Clinical Applications: | | |
| • Fetal/Obstetrics; | ✓ | ✓ |
| • Abdominal/ GYNPediatric; | ✓ | ✓ |
| • Small Organ (breast, testes, thyroid); | ✓ | ✓ |
| • Neonatal Cephalic; | ✓ | ✓ |
| • Adult Cephalic; | ✓ | ✓ |
| • Cardiac (adult and pediatric); | ✓ | ✓ |
| • Peripheral Vascular; | ✓ | ✓ |
| • Musculo-skeletal Conventional and Superficial; | ✓ | ✓ |
| • Urology (including prostate); | ✓ | ✓ |
| • Transesophageal; | ✓ | ✓ |
| • Transrectal; | ✓ | ✓ |
| • Transvaginal; | ✓ | ✓ |
| • Intraoperative (abdominal, thoracic, and vascular). | | ✓ |
| Contact Type<br>• Surface, Cavitary , TEE | ✓ | ✓ |
| Image modes:<br>• B; M; Color, Power, PW& CW Doppler modes, Color M-mode, Harmonic imaging, Combined modes | ✓ | ✓ |
| Transducers | | |
| • 3S-RS | | ✓ |
| • 5S-RS | | ✓ |
| • 6S-RS | ✓ | ✓ |
| • 7S-RS | | ✓ |
| • 10S-RS | | ✓ |
| • M4S-RS | | ✓ |

| | | |
|---|---|---|
| • 4C-RS | ✓ | ✓ |
| • 8C-RS | ✓ | ✓ |
| • E8C-RS | ✓ | ✓ |
| • 8L-RS | | ✓ |
| • 9L-RS | | ✓ |
| • 12L-RS | | ✓ |
| • i12L-RS | | ✓ |
| • 6Tc / 6Tc-RS | ✓ | ✓ |
| • 6T / 6T-RS | | ✓ |
| • 9T / 9T-RS | | ✓ |
| • P2D | ✓ | ✓ |
| • P6D | | ✓ |
| • 3Sc-RS | ✓ | ✓ |
| • 12S-RS | | ✓ |
| • L6-12-RS | ✓ (same transducer as that on the predicate LOGIQ F Series K133034) | |
| Processing &Display features:<br>• Image freeze, Multipleimages, Pan /Zoom, Image maps (color & gray), Cine loop, Spatial & temporal filters, L-R / T-B image rev., LVO Contrast, Digital harmonics, TGC, Raw data access, ATO/ASO, Compound Imaging, Speckle Reduction, B-Flow, Blood Flow Imaging, TSI, TVI/TT, SI/SRI Stress, LOGIQ View, Automated Function Imaging (AFI), AutoEF, CPI (coded phase inversion)<br>• Smart; Depth with synthetic aperture, Clear Vessel, Continuous Tissue; Optimization (CTO), Tissue Characteristic Optimization (TCO) | ✓ | ✓<br>✓ |
| Tested to meet Electrical Safety, EMC and Biocompatibility Standards | ✓ | ✓ |
| Track 3 (within FDA limits) | ✓ | ✓ |

Summary of Non-Clinical Tests:

Vivid T8/Vivid T8 Pro has been evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness as well as thermal, electrical, electromagnetic, and mechanical safety, and have been found to conform with applicable medical device safety standards. The Vivid T8/Vivid T8 Pro complies with voluntary standards:

1. AAMI/ANSI ES60601-1, Medical Electrical Equipment – Part 1: General Requirements for Safety
2. IEC60601-1-2, Medical Electrical Equipment – Part 1-2:General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility Requirements and Tests
3. IEC60601-2-37, Medical Electrical Equipment – Part 2-37:Particular Requirements for the Safety of Ultrasonic Medical Diagnostic and Monitoring Equipment
4. NEMA UD 3, Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
5. ISO10993-1, Biological Evaluation of Medical Devices- Part 1: Evaluation and Testing- Third Edition
6. NEMA UD 2, Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment
7. ISO14971, Application of risk management to medical devices
8. NEMA, Digital Imaging and Communications in Medicine (DICOM) Set. (Radiology)

The following quality assurance measures are applied to the development of the system:

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

- Simulated use testing (Validation)

Transducer material and other patient contact materials such as needle guidance kits are biocompatible.

Summary of Clinical Tests:

The subject of this premarket submission, Vivid T8/Vivid T8 Pro, did not require clinical studies to support substantial equivalence.

Conclusion: GE Healthcare considers the Vivid T8/Vivid T8 Pro to be as safe, as effective, and performance is substantially equivalent to the predicate device(s).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

May 23, 2014

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

Re: K141067
Trade/Device Name: Vivid T8, Vivid T8 Pro Diagnostic Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX
Dated: April 22, 2014
Received: April 24, 2014

Dear Mr. Behn:

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.

This determination of substantial equivalence applies to the following transducers intended for use with the Vivid T8 and Vivid T8 Pro Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

| | |
|---|---|
| 4C-RS | E8C-RS |
| 3Sc-RS | L6-12-RS |
| 8C-RS | P2D |
| 6S-RS | 6Tc-RS |

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" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

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

510(k) Number *(if known)*
K141067

Device Name
Vivid T8/Vivid T8 Pro Diagnostic Ultrasound System

Indications for Use *(Describe)*

The Vivid T8/Vivid T8 Pro is Multipurpose Cardiovascular System designed for cardiac and Shared Service Imaging, the system supports following applications: Fetal/OB, Abdominal, Pediatric, Small Organ, Cardiac, Peripheral Vascular, Adult Cephalic, Neonatal Cephalic, Musculoskeletal Superficial/Conventional, Transcranial, Transrectal, Transvaginal and Transesophageal.

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)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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**

**Vivid T8/Vivid T8 Pro Ultrasound System**

Intended Use: Ultrasound imaging, measurement and analysis of the human body as follows:

| Clinical Application | Mode of Operation | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | Doppler Modes | | | | | Combined Modes* | Harmonic Imaging | Coded Pulse | Other |
| *Anatomy/Region of Interest* | B | M | PW | CW | Color | Color M | Power | | | | |
| Ophthalmic | | | | | | | | | | | |
| Fetal/OB | N | N | N | N | N | N | N | N | N | N | |
| Abdominal[1] | N | N | N | N | N | N | N | N | N | N | |
| Pediatric | N | N | N | N | N | N | N | N | N | N | |
| Small Organ (specify)[2] | N | N | N | | N | N | N | N | N | N | |
| Neonatal Cephalic | N | N | N | N | N | N | N | N | N | N | |
| Adult Cephalic | N | N | N | N | N | N | N | N | N | N | |
| Cardiac[3] | N | N | N | N | N | | N | N | N | N | |
| Peripheral Vascular | N | N | N | | N | N | N | N | N | N | |
| Musculo-skeletal Conventional | N | N | N | | N | N | N | N | N | N | |
| Musculo-skeletal Superficial | N | N | N | | N | N | N | N | N | N | |
| Thoracic/Pleural (specify) | | | | | | | | | | | |
| Other (specify) | | | | | | | | | | | |
| *Exam Type, Means of Access* | | | | | | | | | | | |
| Transcranial | N | N | N | N | N | N | N | N | N | N | |
| Transorbital | | | | | | | | | | | |
| Transesophageal | N | N | N | N | N | N | | N | N | N | |
| Transrectal | N | N | N | | N | N | N | N | N | N | |
| Transvaginal | N | N | N | | N | N | N | N | N | N | |
| Intraoperative (specify) | | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | | |
| Intravascular/Intraluminal | | | | | | | | | | | |
| Intracardiac | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | |

Notes: [1] Abdominal includes GYN and Urological;
[2] Small Organ includes breast, testes, and thyroid;
[3] Cardiac is Adult and Pediatric;
[*] Combined modes are color/power Doppler with B-mode

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

**Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)**

**Prescription Use (Per 21 CFR 801.109)**

**Diagnostic Ultrasound Indications for Use Form**

**Vivid T8/Vivid T8 Pro with 4C-RS Transducer**

Intended Use: Ultrasound imaging, measurement and analysis of the human body as follows:

| Clinical Application | Mode of Operation | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | Doppler Modes | | | | | Combined Modes* | Harmonic Imaging | Coded Pulse | Other |
| *Anatomy/Region of Interest* | B | M | PW | CW | Color | Color M | Power | | | | |
| Ophthalmic | | | | | | | | | | | |
| Fetal/OB | P | P | P | | P | P | P | P | P | P | |
| Abdominal[1] | P | P | P | | P | P | P | P | P | P | |
| Pediatric | | | | | | | | | | | |
| Small Organ (specify)[2] | P | P | P | | P | P | P | P | P | P | |
| Neonatal Cephalic | | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | | |
| Cardiac[3] | | | | | | | | | | | |
| Peripheral Vascular | | | | | | | | | | | |
| Musculo-skeletal Conventional | | | | | | | | | | | |
| Musculo-skeletal Superficial | | | | | | | | | | | |
| Thoracic/Pleural (specify) | | | | | | | | | | | |
| Other (specify) | | | | | | | | | | | |
| *Exam Type, Means of Access* | | | | | | | | | | | |
| Transcranial | | | | | | | | | | | |
| Transorbital | | | | | | | | | | | |
| Transesophageal | | | | | | | | | | | |
| Transrectal | | | | | | | | | | | |
| Transvaginal | | | | | | | | | | | |
| Intraoperative (specify) | | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | | |
| Intravascular/Intraluminal | | | | | | | | | | | |
| Intracardiac | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | |

N = new indication; P = previously cleared by FDA (K121063)

Notes: [1] Abdominal includes GYN and Urological;
[2] Small Organ includes breast, testes, and thyroid;
[3] Cardiac is Adult and Pediatric;
[*] Combined modes are B/M, B/Color M, B/PWD, B/Color/PWD, B/PWD

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**Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)**

**Prescription Use (Per 21 CFR 801.109)**

## Diagnostic Ultrasound Indications for Use Form

## Vivid T8/Vivid T8 Pro with E8C-RS Transducer

Intended Use: Ultrasound imaging, measurement and analysis of the human body as follows:

| Clinical Application | Mode of Operation | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | Doppler Modes | | | | | Combined Modes* | Harmonic Imaging | Coded Pulse | Other |
| *Anatomy/Region of Interest* | B | M | PW | CW | Color | Color M | Power | | | | |
| Ophthalmic | | | | | | | | | | | |
| Fetal/OB | P | P | P | | P | P | P | P | P | P | |
| Abdominal[1] | P | P | P | | P | P | P | P | P | P | |
| Pediatric | | | | | | | | | | | |
| Small Organ (specify)[2] | | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | | |
| Cardiac[3] | | | | | | | | | | | |
| Peripheral Vascular | | | | | | | | | | | |
| Musculo-skeletal Conventional | | | | | | | | | | | |
| Musculo-skeletal Superficial | | | | | | | | | | | |
| Thoracic/Pleural (specify) | | | | | | | | | | | |
| Other (specify) | | | | | | | | | | | |
| *Exam Type, Means of Access* | | | | | | | | | | | |
| Transcranial | | | | | | | | | | | |
| Transorbital | | | | | | | | | | | |
| Transesophageal | | | | | | | | | | | |
| Transrectal | P | P | P | | P | P | P | P | P | P | |
| Transvaginal | P | P | P | | P | P | P | P | P | P | |
| Intraoperative (specify) | | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | | |
| Intravascular/Intraluminal | | | | | | | | | | | |
| Intracardiac | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | |

N = new indication; P = previously cleared by FDA (K121063)

Notes: [1] Abdominal includes GYN and Urological;
[2] Small Organ includes breast, testes, and thyroid
[3] Cardiac is Adult and Pediatric;
[*] Combined modes are B/M, B/Color M, B/PWD, B/Color/PWD, B/PWD

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

**Prescription Use (Per 21 CFR 801.109)**

**Diagnostic Ultrasound Indications for Use Form**

**Vivid T8/Vivid T8 Pro with 3Sc-RS Transducer**

Intended Use: Ultrasound imaging, measurement and analysis of the human body as follows:

| Clinical Application | Mode of Operation | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | Doppler Modes | | | | | Combined Modes* | Harmonic Imaging | Coded Pulse | Other |
| *Anatomy/Region of Interest* | B | M | PW | CW | Color | Color M | Power | | | | |
| Ophthalmic | | | | | | | | | | | |
| Fetal/OB | | | | | | | | | | | |
| Abdominal[1] | P | P | P | P | P | P | P | P | P | P | |
| Pediatric | P | P | P | P | P | P | | P | P | P | |
| Small Organ (specify)[2] | | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | | |
| Adult Cephalic | P | P | P | P | P | P | P | P | P | P | |
| Cardiac[3] | P | P | P | P | P | P | | P | P | P | |
| Peripheral Vascular | | | | | | | | | | | |
| Musculo-skeletal Conventional | | | | | | | | | | | |
| Musculo-skeletal Superficial | | | | | | | | | | | |
| Thoracic/Pleural (specify) | | | | | | | | | | | |
| Other (specify) | | | | | | | | | | | |
| *Exam Type, Means of Access* | | | | | | | | | | | |
| Transcranial | N | N | N | N | N | N | N | N | N | N | |
| Transorbital | | | | | | | | | | | |
| Transesophageal | | | | | | | | | | | |
| Transrectal | | | | | | | | | | | |
| Transvaginal | | | | | | | | | | | |
| Intraoperative (specify) | | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | | |
| Intravascular/Intraluminal | | | | | | | | | | | |
| Intracardiac | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | |

N = new indication; P = previously cleared by FDA (K121063)

Notes: [1] Abdominal includes GYN and Urological
[2] Small Organ includes breast, testes, and thyroid
[3] Cardiac is Adult and Pediatric
[*] Combined modes are B/M, B/Color M, B/PWD, B/Color/PWD, B/PWD

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**Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)**

**Prescription Use (Per 21 CFR 801.109)**

**Diagnostic Ultrasound Indications for Use Form**

**Vivid T8/Vivid T8 Pro with L6-12-RS Transducer**

Intended Use: Ultrasound imaging, measurement and analysis of the human body as follows:

| Clinical Application | Mode of Operation | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | Doppler Modes | | | | | Combined Modes* | Harmonic Imaging | Coded Pulse | Other |
| *Anatomy/Region of Interest* | B | M | PW | CW | Color | Color M | Power | | | | |
| Ophthalmic | | | | | | | | | | | |
| Fetal/OB | | | | | | | | | | | |
| Abdominal[1] | N | N | N | | N | N | N | N | N | N | |
| Pediatric | P | N | P | | P | N | P | P | P | N | |
| Small Organ (specify)[2] | P | N | P | | P | N | P | P | P | N | |
| Neonatal Cephalic | N | N | N | | N | N | N | N | N | N | |
| Adult Cephalic | | | | | | | | | | | |
| Cardiac[3] | | | | | | | | | | | |
| Peripheral Vascular | P | N | P | | P | N | P | P | P | N | |
| Musculo-skeletal Conventional | P | N | P | | P | N | P | P | P | N | |
| Musculo-skeletal Superficial | P | N | P | | P | N | P | P | P | N | |
| Thoracic/Pleural (specify) | | | | | | | | | | | |
| Other (specify) | | | | | | | | | | | |
| *Exam Type, Means of Access* | | | | | | | | | | | |
| Transcranial | | | | | | | | | | | |
| Transorbital | | | | | | | | | | | |
| Transesophageal | | | | | | | | | | | |
| Transrectal | | | | | | | | | | | |
| Transvaginal | | | | | | | | | | | |
| Intraoperative (specify) | | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | | |
| Intravascular/Intraluminal | | | | | | | | | | | |
| Intracardiac | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | |

N = new indication; P = previously cleared by FDA (K133034)

Notes: [1] Abdominal includes GYN and Urological;
[2] Small Organ includes breast, testes, and thyroid;
[3] Cardiac is Adult and Pediatric;
[*] Combined modes are B/M, B/Color M, B/PWD, B/Color/PWD, B/PWD

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**Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)**

**Prescription Use (Per 21 CFR 801.109)**

**Diagnostic Ultrasound Indications for Use Form**

**Vivid T8/Vivid T8 Pro with 8C-RS Transducer**

Intended Use: Ultrasound imaging, measurement and analysis of the human body as follows:

| Clinical Application | Mode of Operation | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | Doppler Modes | | | | | Combined Modes* | Harmonic Imaging | Coded Pulse | Other |
| *Anatomy/Region of Interest* | B | M | PW | CW | Color | Color M | Power | | | | |
| Ophthalmic | | | | | | | | | | | |
| Fetal/OB | | | | | | | | | | | |
| Abdominal[1] | | | | | | | | | | | |
| Pediatric | P | P | P | | P | P | P | P | P | P | |
| Small Organ (specify)[2] | | | | | | | | | | | |
| Neonatal Cephalic | P | P | P | | P | P | P | P | P | P | |
| Adult Cephalic | | | | | | | | | | | |
| Cardiac[3] | | | | | | | | | | | |
| Peripheral Vascular | P | P | P | | P | P | P | P | P | P | |
| Musculo-skeletal Conventional | | | | | | | | | | | |
| Musculo-skeletal Superficial | | | | | | | | | | | |
| Thoracic/Pleural (specify) | | | | | | | | | | | |
| Other (specify) | | | | | | | | | | | |
| *Exam Type, Means of Access* | | | | | | | | | | | |
| Transcranial | | | | | | | | | | | |
| Transorbital | | | | | | | | | | | |
| Transesophageal | | | | | | | | | | | |
| Transrectal | | | | | | | | | | | |
| Transvaginal | | | | | | | | | | | |
| Intraoperative (specify) | | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | | |
| Intravascular/Intraluminal | | | | | | | | | | | |
| Intracardiac | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | |

N = new indication; P = previously cleared by FDA (K121063)

Notes: [1] Abdominal includes GYN and Urological;
[2] Small Organ includes breast, testes, thyroid;
[3] Cardiac is Adult and Pediatric;
[*] Combined modes are B/M, B/Color M, B/PWD, B/Color/PWD, B/PWD

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**Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)**

**Prescription Use (Per 21 CFR 801.109)**

## Diagnostic Ultrasound Indications for Use Form

## Vivid T8/Vivid T8 Pro with P2D Transducer

Intended Use: Ultrasound imaging, measurement and analysis of the human body as follows:

| Clinical Application | Mode of Operation | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | Doppler Modes | | | | | Combined Modes* | Harmonic Imaging | Coded Pulse | Other |
| *Anatomy/Region of Interest* | B | M | PW | CW | Color | Color M | Power | | | | |
| Ophthalmic | | | | | | | | | | | |
| Fetal/OB | | | | | | | | | | | |
| Abdominal[1] | | | | | | | | | | | |
| Pediatric | | | | | | | | | | | |
| Small Organ (specify)[2] | | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | | |
| Cardiac[3] | | | | P | | | | | | | |
| Peripheral Vascular | | | | | | | | | | | |
| Musculo-skeletal Conventional | | | | | | | | | | | |
| Musculo-skeletal Superficial | | | | | | | | | | | |
| Thoracic/Pleural (specify) | | | | | | | | | | | |
| Other (specify) | | | | | | | | | | | |
| *Exam Type, Means of Access* | | | | | | | | | | | |
| Transcranial | | | | | | | | | | | |
| Transorbital | | | | | | | | | | | |
| Transesophageal | | | | | | | | | | | |
| Transrectal | | | | | | | | | | | |
| Transvaginal | | | | | | | | | | | |
| Intraoperative (specify) | | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | | |
| Intravascular/Intraluminal | | | | | | | | | | | |
| Intracardiac | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | |

N = new indication; P = previously cleared by FDA (K121063)

Notes: [1] Abdominal includes GYN and Urological;
[2] Small Organ includes breast, testes, thyroid;
[3] Cardiac is Adult and Pediatric;
[*] Combined modes are B/M, B/Color M, B/PWD, B/Color/PWD, B/PWD

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**Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)**

**Prescription Use (Per 21 CFR 801.109)**

**Diagnostic Ultrasound Indications for Use Form**

**Vivid T8/Vivid T8 Pro with 6S-RS Transducer**

Intended Use: Ultrasound imaging, measurement and analysis of the human body as follows:

| Clinical Application | Mode of Operation | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | Doppler Modes | | | | | Combined Modes* | Harmonic Imaging | Coded Pulse* | Other |
| *Anatomy/Region of Interest* | B | M | PW | CW | Color | Color M | Power | | | | |
| Ophthalmic | | | | | | | | | | | |
| Fetal/OB | P | P | P | P | P | P | | P | P | P | |
| Abdominal[1] | P | P | P | P | P | P | P | P | P | P | |
| Pediatric | P | P | P | P | P | P | P | P | P | P | |
| Small Organ (specify)[2] | | | | | | | | | | | |
| Neonatal Cephalic | P | P | P | P | P | P | P | P | P | P | |
| Adult Cephalic | | | | | | | | | | | |
| Cardiac[3] | P | P | P | P | P | P | | P | P | P | |
| Peripheral Vascular | | | | | | | | | | | |
| Musculo-skeletal Conventional | | | | | | | | | | | |
| Musculo-skeletal Superficial | | | | | | | | | | | |
| Thoracic/Pleural (specify) | | | | | | | | | | | |
| Other (specify) | | | | | | | | | | | |
| *Exam Type, Means of Access* | | | | | | | | | | | |
| Transcranial | | | | | | | | | | | |
| Transorbital | | | | | | | | | | | |
| Transesophageal | | | | | | | | | | | |
| Transrectal | | | | | | | | | | | |
| Transvaginal | | | | | | | | | | | |
| Intraoperative (specify) | | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | | |
| Intravascular/Intraluminal | | | | | | | | | | | |
| Intracardiac | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | |

N = new indication; P = previously cleared by FDA

Notes: [1] Abdominal includes GYN and Urological;
[2] Small Organ includes breast, testes, thyroid;
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[*] Combined modes are B/M, B/Color M, B/PWD, B/Color/PWD, B/PWD

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**Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)**

**Prescription Use (Per 21 CFR 801.109)**

**Diagnostic Ultrasound Indications for Use Form**

**Vivid T8/Vivid T8 Pro with 6Tc-RS Transducer**

Intended Use: Ultrasound imaging, measurement and analysis of the human body as follows:

| Clinical Application | Mode of Operation | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | Doppler Modes | | | | | Combined Modes* | Harmonic Imaging | Coded Pulse | Other |
| *Anatomy/Region of Interest* | B | M | PW | CW | Color | Color M | Power | | | | |
| Ophthalmic | | | | | | | | | | | |
| Fetal/OB | | | | | | | | | | | |
| Abdominal[1] | | | | | | | | | | | |
| Pediatric | | | | | | | | | | | |
| Small Organ (specify)[2] | | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | | |
| Cardiac[3] | P | P | P | P | P | P | | P | P | P | |
| Peripheral Vascular | | | | | | | | | | | |
| Musculo-skeletal Conventional | | | | | | | | | | | |
| Musculo-skeletal Superficial | | | | | | | | | | | |
| Thoracic/Pleural (specify) | | | | | | | | | | | |
| Other (specify) | | | | | | | | | | | |
| *Exam Type, Means of Access* | | | | | | | | | | | |
| Transcranial | | | | | | | | | | | |
| Transorbital | | | | | | | | | | | |
| Transesophageal | P | P | P | P | P | P | | P | P | P | |
| Transrectal | | | | | | | | | | | |
| Transvaginal | | | | | | | | | | | |
| Intraoperative (specify) | | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | | |
| Intravascular/Intraluminal | | | | | | | | | | | |
| Intracardiac | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | |

N = new indication; P = previously cleared by FDA (K121063)

Notes: [1] Abdominal includes GYN and Urological
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[*] Combined modes are B/M, B/Color M, B/PWD, B/Color/PWD, B/PWD

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**Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)**

**Prescription Use (Per 21 CFR 801.109)**

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