



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

GE Medical Systems Ultrasound and Primary Care Diagnostics, LLC
% Ms. Tracey Ortiz
Regulatory Affairs Director
9900 W. Innovation Drive
WAUWATOSA WI 53226

August 5, 2016

Re: K161706
Trade/Device Name: Vivid *iq*
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX
Dated: June 16, 2016
Received: June 20, 2016

Dear Ms. Ortiz:

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



GE Healthcare
510(k) Premarket Notification Submission

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

Indications for Use

510(k) Number (if known)

K161706

Device Name

Vivid iq

Indications for Use (Describe)

The Vivid iq is a high-performance compact ultrasound system designed for cardiovascular and shared services applications. The indications of the product will include Fetal, OB, Abdominal, Pediatric, small Organ, Neonatal Cephalic, Adult Cephalic, Cardiac, Peripheral Vascular, Musculo-skeletal Conventional, Musculo-skeletal Superficial, Transcranial, Transrectal, Transvaginal, Transesophageal, Tissue biopsy, Intraoperative, IntraCardiac and Intraluminal.

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)



GE Healthcare
510(k) Premarket Notification Submission

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."



Indications for Use Forms

The following forms represent indications with clinical applications and exam types along with the modes of operation for the Vivid *iq*. Combinations identified “P” represents those previously cleared with another GE Ultrasound system. Combinations identified as “N” are new.

The following Indication for Use forms are appended:

System: Vivid *iq*

Transducer: 3Sc-RS

Transducer: M5Sc-RS

Transducer: 6S-RS

Transducer: 12S-RS

Transducer: 6Tc-RS

Transducer: 6VT-D

Transducer: P2D

Transducer: 9T-RS

Transducer: AcuNav 10F (G version)

Transducer: AcuNav 8F (G version)

Transducer: SOUNDSTAR 3D 10F (G version)

Transducer: SOUNDSTAR eco 8F (G version)

Transducer: SOUNDSTAR eco 10F (G version)

Transducer: 9L-RS

Transducer: 12L-RS

Transducer: ML6-15-RS

Transducer: L8-18i-RS

Transducer: 4C-RS

Transducer: C1-5-RS

Transducer: E8Cs-RS

Transducer: 8C-RS



Diagnostic Ultrasound Indications for Use Form

GE Vivid iq Diagnostic Ultrasound System

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

Clinical Application	Mode of Operation										
	B	M	PW	CW	Color	Color M	PDI	Combined Modes*	Harmonic Imaging	Coded Pulse**	RT 3D Mode
<i>Anatomy/Region of Interest</i>											
Ophthalmic											
Fetal / Obstetrics	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 ^[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		
Cardiac ^[3]	N	N	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	
Other (specify)											
<i>Exam Type, Means of Access</i>											
Transcranial	N	N	N	N	N	N	N	N	N	N	
Transesophageal	N	N	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 ^[4]	N	N	N	N	N	N	N	N	N	N	
<i>Interventional Guidance</i>											
Intracardiac and Intraluminal	N	N	N	N	N	N	N	N	N		
Tissue Biopsy ^[5]	N	N		N		N	N	N	N	N	
Vascular Access (IV, PICC)											

N= new indication; P= previously cleared by FDA K121062; P¹ = previously cleared by FDA K150087; P²=previously cleared by FDA K160184; P³ = previously cleared by FDA K160277; P⁴ = previously cleared by FDA K160078; P⁵ = previously cleared by FDA K140318 by Biosense Webster, Inc.

- Notes: [1] Abdominal includes GYN and Urological; [2] Small Organ includes breast, testes, thyroid;
 [3] Cardiac is Adult and Pediatric;
 [4] Intraoperative includes thoracic(cardiac) and vascular (PV);
 [5] Includes image guidance for freehand needle placement;
 [*]Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD;
 [**] Coded Pulse is for digitally encoded harmonics.

(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

GE Vivid iq with 3Sc-RS Transducer

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

Clinical Application	Mode of Operation										
	B	M	PW	CW	Color	Color M	PDI	Combined Modes*	Harmonic Imaging	Coded Pulse**	RT 3D Mode
<i>Anatomy/Region of Interest</i>											
Ophthalmic											
Fetal / Obstetrics	P	P	P	P	P	P	P ²	P	P		
Abdominal ^[1]	P	P	P	P	P	P	P	P	P		
Pediatric	P	P	P	P	P	P	P	P	P		
Small Organ ^[2]											
Neonatal Cephalic											
Adult Cephalic	P	P	P	P	P	P	P	P	P		
Cardiac ^[3]	P	P	P	P	P	P	P ³	P	P		
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)											
<i>Exam Type, Means of Access</i>											
Transcranial	P ⁴	P ⁴	P ⁴	P ⁴	P ⁴	P ⁴	P ⁴	P ⁴	P ⁴		
Transesophageal											
Transrectal											
Transvaginal											
Intraoperative ^[4]											
<i>Interventional Guidance</i>											
Intracardiac and Intraluminal											
Tissue Biopsy ^[5]	P ⁴	P ⁴		N		P ⁴	P ⁴	P ⁴	P ⁴		
Vascular Access (IV, PICC)											

N= new indication; P= previously cleared by FDA K121062; P¹ = previously cleared by FDA K150087; P²=previously cleared by FDA K160184; P³ = previously cleared by FDA K160277; P⁴ = previously cleared by FDA K160078; P⁵ = previously cleared by FDA K140318 by Biosense Webster, Inc.

Notes: [1] Abdominal includes GYN and Urological; [2] Small Organ includes breast, testes, thyroid; [3] Cardiac is Adult and Pediatric; [4] Intraoperative includes thoracic(cardiac) and vascular (PV); [5] Includes image guidance for freehand needle placement; [*]Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD; [**] Coded Pulse is for digitally encoded harmonics.

(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

GE Vivid iq with M5Sc-RS Transducer

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

Clinical Application	Mode of Operation										
	B	M	PW	CW	Color	Color M	PDI	Combined Modes*	Harmonic Imaging	Coded Pulse**	RT 3D Mode
<i>Anatomy/Region of Interest</i>											
Ophthalmic											
Fetal / Obstetrics	N	N	N	N	N	N	N	N	N		
Abdominal ^[1]	N	N	N	N	N	N	N	N	N		
Pediatric	N	N	N	N	N	N	N	N	N		
Small Organ ^[2]											
Neonatal Cephalic											
Adult Cephalic	N	N	N	N	N	N	N	N	N		
Cardiac ^[3]	N	N	N	N	N	N	N	N	N		
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)											
<i>Exam Type, Means of Access</i>											
Transcranial	N	N	N	N	N	N	N	N	N		
Transesophageal											
Transrectal											
Transvaginal											
Intraoperative ^[4]											
<i>Interventional Guidance</i>											
Intracardiac and Intraluminal											
Tissue Biopsy ^[5]	N	N	N		N	N	N	N	N		
Vascular Access (IV, PICC)											

N= new indication; P= previously cleared by FDA K121062; P¹ = previously cleared by FDA K150087; P²=previously cleared by FDA K160184; P³ = previously cleared by FDA K160277; P⁴ = previously cleared by FDA K160078; P⁵ = previously cleared by FDA K140318 by Biosense Webster, Inc.

Notes: [1] Abdominal includes GYN and Urological; [2] Small Organ includes breast, testes, thyroid; [3] Cardiac is Adult and Pediatric; [4] Intraoperative includes thoracic(cardiac) and vascular (PV); [5] Includes image guidance for freehand needle placement; [*]Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD; [**] Coded Pulse is for digitally encoded harmonics.

(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

GE Vivid iq with 6S-RS Transducer

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

Clinical Application	Mode of Operation										
	B	M	PW	CW	Color	Color M	PDI	Combined Modes*	Harmonic Imaging	Coded Pulse**	RT 3D Mode
<i>Anatomy/Region of Interest</i>											
Ophthalmic											
Fetal / Obstetrics	P	P	P	P	P	P	P	P	P		
Abdominal ^[1]	P	P	P	P	P	P	P	P	P		
Pediatric	P	P	P	P	P	P	P	P	P		
Small Organ ^[2]											
Neonatal Cephalic	P	P	P	P	P	P	P	P	P		
Adult Cephalic											
Cardiac ^[3]											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)											
<i>Exam Type, Means of Access</i>											
Transcranial	P ³	P ³	P ³	P ³	P ³	P ³	P ³	P ³	P ³		
Transesophageal											
Transrectal											
Transvaginal											
Intraoperative ^[4]											
<i>Interventional Guidance</i>											
Intracardiac and Intraluminal											
Tissue Biopsy ^[5]											
Vascular Access (IV, PICC)											

N= new indication; P= previously cleared by FDA K121062; P¹ = previously cleared by FDA K150087; P²=previously cleared by FDA K160184; P³ = previously cleared by FDA K160277; P⁴ = previously cleared by FDA K160078; P⁵ = previously cleared by FDA K140318 by Biosense Webster, Inc .

Notes: [1] Abdominal includes GYN and Urological; [2] Small Organ includes breast, testes, thyroid; [3] Cardiac is Adult and Pediatric; [4] Intraoperative includes thoracic(cardiac) and vascular (PV); [5] Includes image guidance for freehand needle placement; [*]Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD; [**] Coded Pulse is for digitally encoded harmonics.

(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

GE Vivid iq with 12S-RS Transducer

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

Clinical Application	Mode of Operation										
	B	M	PW	CW	Color	Color M	PDI	Combined Modes*	Harmonic Imaging	Coded Pulse**	RT 3D Mode
<i>Anatomy/Region of Interest</i>											
Ophthalmic											
Fetal / Obstetrics											
Abdominal ^[1]	P	P	P	P	P	P	P	P	P		
Pediatric	P	P	P	P	P	P	P	P	P		
Small Organ ^[2]											
Neonatal Cephalic	P	P	P	P	P	P	P	P	P		
Adult Cephalic											
Cardiac ^[3]											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)											
<i>Exam Type, Means of Access</i>											
Transcranial	N	N	N	N	N	N	N	N	N		
Transesophageal											
Transrectal											
Transvaginal											
Intraoperative ^[4]											
<i>Interventional Guidance</i>											
Intracardiac and Intraluminal											
Tissue Biopsy ^[5]											
Vascular Access (IV, PICC)											

N= new indication; P= previously cleared by FDA K121062; P¹ = previously cleared by FDA K150087; P²=previously cleared by FDA K160184; P³ = previously cleared by FDA K160277; P⁴ = previously cleared by FDA K160078; P⁵ = previously cleared by FDA K140318 by Biosense Webster, Inc.

Notes: [1] Abdominal includes GYN and Urological; [2] Small Organ includes breast, testes, thyroid; [3] Cardiac is Adult and Pediatric; [4] Intraoperative includes thoracic(cardiac) and vascular (PV); [5] Includes image guidance for freehand needle placement; [*]Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD; [**] Coded Pulse is for digitally encoded harmonics.

(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

GE Vivid iq with 6Tc-RS Transducer

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

Clinical Application	Mode of Operation										
	B	M	PW	CW	Color	Color M	PDI	Combined Modes*	Harmonic Imaging	Coded Pulse**	RT 3D Mode
<i>Anatomy/Region of Interest</i>											
Ophthalmic											
Fetal / Obstetrics											
Abdominal ^[1]											
Pediatric											
Small Organ ^[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac ^[3]	P	P	P	P	P	P	P	P	P		
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)											
<i>Exam Type, Means of Access</i>											
Transcranial											
Transesophageal	P	P	P	P	P	P	P	P	P		
Transrectal											
Transvaginal											
Intraoperative ^[4]											
<i>Interventional Guidance</i>											
Intracardiac and Intraluminal											
Tissue Biopsy ^[5]											
Vascular Access (IV, PICC)											

N= new indication; P= previously cleared by FDA K121062; P¹ = previously cleared by FDA K150087; P²=previously cleared by FDA K160184; P³ = previously cleared by FDA K160277; P⁴ = previously cleared by FDA K160078; P⁵ = previously cleared by FDA K140318 by Biosense Webster, Inc.

Notes: [1] Abdominal includes GYN and Urological; [2] Small Organ includes breast, testes, thyroid; [3] Cardiac is Adult and Pediatric; [4] Intraoperative includes thoracic(cardiac) and vascular (PV); [5] Includes image guidance for freehand needle placement; [*]Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD; [**] Coded Pulse is for digitally encoded harmonics.

(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)**



GE Healthcare

510(k) Premarket Notification Submission

Diagnostic Ultrasound Indications for Use Form

GE Vivid iq with 6VT-D Transducer

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

Clinical Application	Mode of Operation											
	B	M	PW	CW	Color	Color M	PDI	Combined Modes*	Harmonic Imaging	Coded Pulse**	RT 3D Mode	
<i>Anatomy/Region of Interest</i>												
Ophthalmic												
Fetal / Obstetrics												
Abdominal ^[1]												
Pediatric												
Small Organ ^[2]												
Neonatal Cephalic												
Adult Cephalic												
Cardiac ^[3]	P ¹	P ¹	P ¹	P ¹	P ¹	P ¹	P ¹	P ¹	P ¹	P ¹		P ¹
Peripheral Vascular												
Musculo-skeletal Conventional												
Musculo-skeletal Superficial												
Other (specify)												
<i>Exam Type, Means of Access</i>												
Transcranial												
Transesophageal	P ¹	P ¹	P ¹	P ¹	P ¹	P ¹	P ¹	P ¹	P ¹	P ¹		P ¹
Transrectal												
Transvaginal												
Intraoperative ^[4]												
<i>Interventional Guidance</i>												
Intracardiac and Intraluminal												
Tissue Biopsy ^[5]												
Vascular Access (IV, PICC)												

N= new indication; P= previously cleared by FDA K121062; P¹ = previously cleared by FDA K150087; P²=previously cleared by FDA K160184; P³ = previously cleared by FDA K160277; P⁴ = previously cleared by FDA K160078; P⁵ = previously cleared by FDA K140318 by Biosense Webster, Inc.

Notes: [1] Abdominal includes GYN and Urological; [2] Small Organ includes breast, testes, thyroid; [3] Cardiac is Adult and Pediatric; [4] Intraoperative includes thoracic(cardiac) and vascular (PV); [5] Includes image guidance for freehand needle placement; [*]Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD; [**] Coded Pulse is for digitally encoded harmonics.

(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)



GE Healthcare

510(k) Premarket Notification Submission

Diagnostic Ultrasound Indications for Use Form

GE Vivid iq with P2D Transducer

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

Clinical Application	Mode of Operation										
	B	M	PW	CW	Color	Color M	PDI	Combined Modes*	Harmonic Imaging	Coded Pulse**	RT 3D Mode
<i>Anatomy/Region of Interest</i>											
Ophthalmic											
Fetal / Obstetrics											
Abdominal ^[1]											
Pediatric											
Small Organ ^[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac ^[3]				P							
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)											
<i>Exam Type, Means of Access</i>											
Transcranial											
Transesophageal											
Transrectal											
Transvaginal											
Intraoperative ^[4]											
<i>Interventional Guidance</i>											
Intracardiac and Intraluminal											
Tissue Biopsy ^[5]											
Vascular Access (IV, PICC)											

N= new indication; P= previously cleared by FDA K121062; P¹ = previously cleared by FDA K150087; P²=previously cleared by FDA K160184; P³ = previously cleared by FDA K160277; P⁴ = previously cleared by FDA K160078; P⁵ = previously cleared by FDA K140318 by Biosense Webster, Inc.

- Notes: [1] Abdominal includes GYN and Urological; [2] Small Organ includes breast, testes, thyroid;
 [3] Cardiac is Adult and Pediatric;
 [4] Intraoperative includes thoracic(cardiac) and vascular (PV);
 [5] Includes image guidance for freehand needle placement;
 [*] Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD;
 [**] Coded Pulse is for digitally encoded harmonics.

(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

GE Vivid iq with 9T-RS Transducer

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

Clinical Application	Mode of Operation											
	B	M	PW	CW	Color	Color M	PDI	Combined Modes*	Harmonic Imaging	Coded Pulse**	RT 3D Mode	
<i>Anatomy/Region of Interest</i>												
Ophthalmic												
Fetal / Obstetrics												
Abdominal ^[1]												
Pediatric												
Small Organ ^[2]												
Neonatal Cephalic												
Adult Cephalic												
Cardiac ^[3]	P	P	P	P	P	P	P ¹	P	P	P ¹		
Peripheral Vascular												
Musculo-skeletal Conventional												
Musculo-skeletal Superficial												
Other (specify)												
<i>Exam Type, Means of Access</i>												
Transcranial												
Transesophageal	P	P	P	P	P	P	P ¹	P	P	P ¹		
Transrectal												
Transvaginal												
Intraoperative ^[4]												
<i>Interventional Guidance</i>												
Intracardiac and Intraluminal												
Tissue Biopsy ^[5]												
Vascular Access (IV, PICC)												

N= new indication; P= previously cleared by FDA K121062; P¹ = previously cleared by FDA K150087; P²=previously cleared by FDA K160184; P³ = previously cleared by FDA K160277; P⁴ = previously cleared by FDA K160078; P⁵ = previously cleared by FDA K140318 by Biosense Webster, Inc.

Notes: [1] Abdominal includes GYN and Urological; [2] Small Organ includes breast, testes, thyroid; [3] Cardiac is Adult and Pediatric; [4] Intraoperative includes thoracic(cardiac) and vascular (PV); [5] Includes image guidance for freehand needle placement; [*]Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD; [**] Coded Pulse is for digitally encoded harmonics.

(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

GE Vivid iq with AcuNav 10F (G version) Transducer

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

Clinical Application	Mode of Operation											
	B	M	PW	CW	Color	Color M	PDI	Combined Modes*	Harmonic Imaging	Coded Pulse**	RT 3D Mode	
<i>Anatomy/Region of Interest</i>												
Ophthalmic												
Fetal / Obstetrics												
Abdominal ^[1]												
Pediatric												
Small Organ ^[2]												
Neonatal Cephalic												
Adult Cephalic												
Cardiac ^[3]												
Peripheral Vascular												
Musculo-skeletal Conventional												
Musculo-skeletal Superficial												
Other (specify)												
<i>Exam Type, Means of Access</i>												
Transcranial												
Transesophageal												
Transrectal												
Transvaginal												
Intraoperative ^[4]	P	P	P	P	P	P	N	P	P			
<i>Interventional Guidance</i>												
Intracardiac and Intraluminal	P	P	P	P	P	P	N	P	P			
Tissue Biopsy ^[5]												
Vascular Access (IV, PICC)												

N= new indication; P= previously cleared by FDA K121062; P¹ = previously cleared by FDA K150087; P²=previously cleared by FDA K160184; P³ = previously cleared by FDA K160277; P⁴ = previously cleared by FDA K160078; P⁵ = previously cleared by FDA K140318 by Biosense Webster, Inc.

Notes: [1] Abdominal includes GYN and Urological; [2] Small Organ includes breast, testes, thyroid; [3] Cardiac is Adult and Pediatric; [4] Intraoperative includes thoracic(cardiac) and vascular (PV); [5] Includes image guidance for freehand needle placement; [*]Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD; [**] Coded Pulse is for digitally encoded harmonics.

(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
GE Vivid iq with AcuNav 8F (G version) Transducer

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

Clinical Application	Mode of Operation										
	B	M	PW	CW	Color	Color M	PDI	Combined Modes*	Harmonic Imaging	Coded Pulse**	RT 3D Mode
<i>Anatomy/Region of Interest</i>											
Ophthalmic											
Fetal / Obstetrics											
Abdominal ^[1]											
Pediatric											
Small Organ ^[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac ^[3]											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)											
<i>Exam Type, Means of Access</i>											
Transcranial											
Transesophageal											
Transrectal											
Transvaginal											
Intraoperative ^[4]	N	N	N	N	N	N	N	N	N		
<i>Interventional Guidance</i>											
Intracardiac and Intraluminal	P	P	P	P	P	P	N	P	P		
Tissue Biopsy ^[5]											
Vascular Access (IV, PICC)											

N= new indication; P= previously cleared by FDA K121062; P¹ = previously cleared by FDA K150087; P²=previously cleared by FDA K160184; P³ = previously cleared by FDA K160277; P⁴ = previously cleared by FDA K160078; P⁵ = previously cleared by FDA K140318 by Biosense Webster, Inc.

Notes: [1] Abdominal includes GYN and Urological; [2] Small Organ includes breast, testes, thyroid; [3] Cardiac is Adult and Pediatric; [4] Intraoperative includes thoracic(cardiac) and vascular (PV); [5] Includes image guidance for freehand needle placement; [*]Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD; [**] Coded Pulse is for digitally encoded harmonics.

(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

GE Vivid iq with SOUNDSTAR 3D 10F (G version) Transducer

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

Clinical Application	Mode of Operation											
	B	M	PW	CW	Color	Color M	PDI	Combined Modes*	Harmonic Imaging	Coded Pulse**	RT 3D Mode	
<i>Anatomy/Region of Interest</i>												
Ophthalmic												
Fetal / Obstetrics												
Abdominal ^[1]												
Pediatric												
Small Organ ^[2]												
Neonatal Cephalic												
Adult Cephalic												
Cardiac ^[3]												
Peripheral Vascular												
Musculo-skeletal Conventional												
Musculo-skeletal Superficial												
Other (specify)												
<i>Exam Type, Means of Access</i>												
Transcranial												
Transesophageal												
Transrectal												
Transvaginal												
Intraoperative ^[4]	N	N	N	N	N	N	N	N	N			
<i>Interventional Guidance</i>												
Intracardiac and Intraluminal	P	P	P	P	P	P	N	P	P			
Tissue Biopsy ^[5]												
Vascular Access (IV, PICC)												

N= new indication; P= previously cleared by FDA K121062; P¹ = previously cleared by FDA K150087; P²=previously cleared by FDA K160184; P³ = previously cleared by FDA K160277; P⁴ = previously cleared by FDA K160078; P⁵ = previously cleared by FDA K140318 by Biosense Webster, Inc.

Notes: [1] Abdominal includes GYN and Urological; [2] Small Organ includes breast, testes, thyroid; [3] Cardiac is Adult and Pediatric; [4] Intraoperative includes thoracic(cardiac) and vascular (PV); [5] Includes image guidance for freehand needle placement; [*]Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD; [**] Coded Pulse is for digitally encoded harmonics.

(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

GE Vivid iq with SOUNDSTAR eco 8F (G version) Transducer

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

Clinical Application	Mode of Operation											
	B	M	PW	CW	Color	Color M	PDI	Combined Modes*	Harmonic Imaging	Coded Pulse**	RT 3D Mode	
<i>Anatomy/Region of Interest</i>												
Ophthalmic												
Fetal / Obstetrics												
Abdominal ^[1]												
Pediatric												
Small Organ ^[2]												
Neonatal Cephalic												
Adult Cephalic												
Cardiac ^[3]												
Peripheral Vascular												
Musculo-skeletal Conventional												
Musculo-skeletal Superficial												
Other (specify)												
<i>Exam Type, Means of Access</i>												
Transcranial												
Transesophageal												
Transrectal												
Transvaginal												
Intraoperative ^[4]	N	N	N	N	N	N	N	N	N	N		
<i>Interventional Guidance</i>												
Intracardiac and Intraluminal	P ⁵	P ⁵	P ⁵	P ⁵	P ⁵	P ⁵	P ⁵	P ⁵	P ⁵	P ⁵		
Tissue Biopsy ^[5]												
Vascular Access (IV, PICC)												

N= new indication; P= previously cleared by FDA K121062; P¹ = previously cleared by FDA K150087; P²=previously cleared by FDA K160184; P³ = previously cleared by FDA K160277; P⁴ = previously cleared by FDA K160078; P⁵ = previously cleared by FDA K140318 by Biosense Webster, Inc.

Notes: [1] Abdominal includes GYN and Urological; [2] Small Organ includes breast, testes, thyroid; [3] Cardiac is Adult and Pediatric; [4] Intraoperative includes thoracic(cardiac) and vascular (PV); [5] Includes image guidance for freehand needle placement; [*]Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD; [**] Coded Pulse is for digitally encoded harmonics.

(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

GE Vivid iq with SOUNDSTAR eco 10F (G version) Transducer

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

Clinical Application	Mode of Operation											
	B	M	PW	CW	Color	Color M	PDI	Combined Modes*	Harmonic Imaging	Coded Pulse**	RT 3D Mode	
<i>Anatomy/Region of Interest</i>												
Ophthalmic												
Fetal / Obstetrics												
Abdominal ^[1]												
Pediatric												
Small Organ ^[2]												
Neonatal Cephalic												
Adult Cephalic												
Cardiac ^[3]												
Peripheral Vascular												
Musculo-skeletal Conventional												
Musculo-skeletal Superficial												
Other (specify)												
<i>Exam Type, Means of Access</i>												
Transcranial												
Transesophageal												
Transrectal												
Transvaginal												
Intraoperative ^[4]	N	N	N	N	N	N	N	N	N			
<i>Interventional Guidance</i>												
Intracardiac and Intraluminal	P	P	P	P	P	P	N	P	P			
Tissue Biopsy ^[5]												
Vascular Access (IV, PICC)												

N= new indication; P= previously cleared by FDA K121062; P¹ = previously cleared by FDA K150087; P²=previously cleared by FDA K160184; P³ = previously cleared by FDA K160277; P⁴ = previously cleared by FDA K160078; P⁵ = previously cleared by FDA K140318 by Biosense Webster, Inc.

Notes: [1] Abdominal includes GYN and Urological; [2] Small Organ includes breast, testes, thyroid; [3] Cardiac is Adult and Pediatric; [4] Intraoperative includes thoracic(cardiac) and vascular (PV); [5] Includes image guidance for freehand needle placement; [*]Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD; [**] Coded Pulse is for digitally encoded harmonics.

(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

GE Vivid iq with 9L-RS Transducer

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

Clinical Application	Mode of Operation										
	B	M	PW	CW	Color	Color M	PDI	Combined Modes*	Harmonic Imaging	Coded Pulse**	RT 3D Mode
<i>Anatomy/Region of Interest</i>											
Ophthalmic											
Fetal / Obstetrics											
Abdominal ^[1]	P	P	P		P		P	P	P	P	
Pediatric	P	P	P		P		P	P	P	P	
Small Organ ^[2]	P	P	P		P		P	P	P	P	
Neonatal Cephalic	P ⁴	P ⁴	P ⁴		P ⁴		P ⁴	P ⁴	P ⁴	P ⁴	
Adult Cephalic											
Cardiac ^[3]											
Peripheral Vascular	P	P	P		P		P	P	P	P	
Musculo-skeletal Conventional	P	P	P		P		P	P	P	P	
Musculo-skeletal Superficial	P	P	P		P		P	P	P	P	
Other (specify)											
<i>Exam Type, Means of Access</i>											
Transcranial											
Transesophageal											
Transrectal											
Transvaginal											
Intraoperative ^[4]											
<i>Interventional Guidance</i>											
Intracardiac and Intraluminal											
Tissue Biopsy ^[5]	P ⁴	P ⁴	P ⁴		P ⁴		P ⁴	P ⁴	P ⁴	P ⁴	
Vascular Access (IV, PICC)											

N= new indication; P= previously cleared by FDA K121062; P¹ = previously cleared by FDA K150087; P²=previously cleared by FDA K160184; P³ = previously cleared by FDA K160277; P⁴ = previously cleared by FDA K160078; P⁵ = previously cleared by FDA K140318 by Biosense Webster, Inc.

Notes: [1] Abdominal includes GYN and Urological; [2] Small Organ includes breast, testes, thyroid; [3] Cardiac is Adult and Pediatric; [4] Intraoperative includes thoracic(cardiac) and vascular (PV); [5] Includes image guidance for freehand needle placement; [*]Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD; [**] Coded Pulse is for digitally encoded harmonics.

(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

GE Vivid iq with 12L-RS Transducer

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

Clinical Application	Mode of Operation										
	B	M	PW	CW	Color	Color M	PDI	Combined Modes*	Harmonic Imaging	Coded Pulse**	RT 3D Mode
<i>Anatomy/Region of Interest</i>											
Ophthalmic											
Fetal / Obstetrics											
Abdominal ^[1]	P	P	P		P		P	P	P	P	
Pediatric	P	P	P		P		P	P	P	P	
Small Organ ^[2]	P	P	P		P		P	P	P	P	
Neonatal Cephalic	P ⁴	P ⁴	P ⁴		P ⁴		P ⁴	P ⁴	P ⁴	P ⁴	
Adult Cephalic											
Cardiac ^[3]											
Peripheral Vascular	P	P	P		P		P	P	P	P	
Musculo-skeletal Conventional	P	P	P		P		P	P	P	P	
Musculo-skeletal Superficial	P	P	P		P		P	P	P	P	
Other (specify)											
<i>Exam Type, Means of Access</i>											
Transcranial											
Transesophageal											
Transrectal											
Transvaginal											
Intraoperative ^[4]											
<i>Interventional Guidance</i>											
Intracardiac and Intraluminal											
Tissue Biopsy ^[5]	P ⁴	P ⁴	P ⁴		P ⁴		P ⁴	P ⁴	P ⁴	P ⁴	
Vascular Access (IV, PICC)											

N= new indication; P= previously cleared by FDA K121062; P¹ = previously cleared by FDA K150087; P²=previously cleared by FDA K160184; P³ = previously cleared by FDA K160277; P⁴ = previously cleared by FDA K160078; P⁵ = previously cleared by FDA K140318 by Biosense Webster, Inc.

Notes: [1] Abdominal includes GYN and Urological; [2] Small Organ includes breast, testes, thyroid; [3] Cardiac is Adult and Pediatric; [4] Intraoperative includes thoracic(cardiac) and vascular (PV); [5] Includes image guidance for freehand needle placement; [*]Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD; [**] Coded Pulse is for digitally encoded harmonics.

(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

GE Vivid iq with ML6-15-RS Transducer

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

Clinical Application	Mode of Operation										
	B	M	PW	CW	Color	Color M	PDI	Combined Modes*	Harmonic Imaging	Coded Pulse**	RT 3D Mode
<i>Anatomy/Region of Interest</i>											
Ophthalmic											
Fetal / Obstetrics											
Abdominal ^[1]	P ²	P ²	P ²		P ²		P ²	P ²	P ²	P ²	
Pediatric	P ²	P ²	P ²		P ²		P ²	P ²	P ²	P ²	
Small Organ ^[2]	P ²	P ²	P ²		P ²		P ²	P ²	P ²	P ²	
Neonatal Cephalic	N	N	N		N		N	N	N	N	
Adult Cephalic											
Cardiac ^[3]											
Peripheral Vascular	P ²	P ²	P ²		P ²		P ²	P ²	P ²	P ²	
Musculo-skeletal Conventional	P ²	P ²	P ²		P ²		P ²	P ²	P ²	P ²	
Musculo-skeletal Superficial	P ²	P ²	P ²		P ²		P ²	P ²	P ²	P ²	
Other (specify)											
<i>Exam Type, Means of Access</i>											
Transcranial											
Transesophageal											
Transrectal											
Transvaginal											
Intraoperative ^[4]											
<i>Interventional Guidance</i>											
Intracardiac and Intraluminal											
Tissue Biopsy ^[5]	N	N	N		N		N	N	N	N	
Vascular Access (IV, PICC)											

N= new indication; P= previously cleared by FDA K121062; P¹ = previously cleared by FDA K150087; P²=previously cleared by FDA K160184; P³ = previously cleared by FDA K160277; P⁴ = previously cleared by FDA K160078; P⁵ = previously cleared by FDA K140318 by Biosense Webster, Inc.

Notes: [1] Abdominal includes GYN and Urological; [2] Small Organ includes breast, testes, thyroid; [3] Cardiac is Adult and Pediatric; [4] Intraoperative includes thoracic(cardiac) and vascular (PV); [5] Includes image guidance for freehand needle placement; [*]Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD; [**] Coded Pulse is for digitally encoded harmonics.

(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

GE Vivid iq with L8-18i-RS Transducer

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

Clinical Application	Mode of Operation										
	B	M	PW	CW	Color	Color M	PDI	Combined Modes*	Harmonic Imaging	Coded Pulse**	RT 3D Mode
<i>Anatomy/Region of Interest</i>											
Ophthalmic											
Fetal / Obstetrics											
Abdominal ^[1]											
Pediatric											
Small Organ ^[2]	P ³	P ³	P ³		P ³	N	P ³	P ³	P ³	N	
Neonatal Cephalic											
Adult Cephalic											
Cardiac ^[3]											
Peripheral Vascular	P ³	P ³	P ³		P ³	N	P ³	P ³	P ³	N	
Musculo-skeletal Conventional	N	N	N		N	N	N	N	N	N	
Musculo-skeletal Superficial	P ³	P ³	P ³		P ³	N	P ³	P ³	P ³	N	
Other (specify)											
<i>Exam Type, Means of Access</i>											
Transcranial											
Transesophageal											
Transrectal											
Transvaginal											
Intraoperative ^[4]	N	N	N		N	N	N	N	N	N	
<i>Interventional Guidance</i>											
Intracardiac and Intraluminal											
Tissue Biopsy ^[5]											
Vascular Access (IV, PICC)											

N= new indication; P= previously cleared by FDA K121062; P¹ = previously cleared by FDA K150087; P²=previously cleared by FDA K160184; P³ = previously cleared by FDA K160277; P⁴ = previously cleared by FDA K160078; P⁵ = previously cleared by FDA K140318 by Biosense Webster, Inc.

Notes: [1] Abdominal includes GYN and Urological; [2] Small Organ includes breast, testes, thyroid; [3] Cardiac is Adult and Pediatric; [4] Intraoperative includes thoracic(cardiac) and vascular (PV); [5] Includes image guidance for freehand needle placement; [*]Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD; [**] Coded Pulse is for digitally encoded harmonics.

(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

GE Vivid iq with 4C-RS Transducer

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

Clinical Application	Mode of Operation										
	B	M	PW	CW	Color	Color M	PDI	Combined Modes*	Harmonic Imaging	Coded Pulse**	RT 3D Mode
<i>Anatomy/Region of Interest</i>											
Ophthalmic											
Fetal / Obstetrics	P	P	P		P	P	P	P	P	P	
Abdominal ^[1]	P	P	P		P	P	P	P	P	P	
Pediatric	P ⁴	P ⁴	P ⁴		P ⁴	N	P ⁴	P ⁴	P ⁴	P ⁴	
Small Organ ^[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac ^[3]											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)											
<i>Exam Type, Means of Access</i>											
Transcranial											
Transesophageal											
Transrectal											
Transvaginal											
Intraoperative ^[4]											
<i>Interventional Guidance</i>											
Intracardiac and Intraluminal											
Tissue Biopsy ^[5]	P ⁴	P ⁴	N		P ⁴	N	P ⁴	P ⁴	P ⁴	P ⁴	
Vascular Access (IV, PICC)											

N= new indication; P= previously cleared by FDA K121062; P¹ = previously cleared by FDA K150087; P²=previously cleared by FDA K160184; P³ = previously cleared by FDA K160277; P⁴ = previously cleared by FDA K160078; P⁵ = previously cleared by FDA K140318 by Biosense Webster, Inc.

Notes: [1] Abdominal includes GYN and Urological; [2] Small Organ includes breast, testes, thyroid; [3] Cardiac is Adult and Pediatric; [4] Intraoperative includes thoracic(cardiac) and vascular (PV); [5] Includes image guidance for freehand needle placement; [*]Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD; [**] Coded Pulse is for digitally encoded harmonics.

(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

GE Vivid iq with C1-5-RS Transducer

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

Clinical Application	Mode of Operation										
	B	M	PW	CW	Color	Color M	PDI	Combined Modes*	Harmonic Imaging	Coded Pulse**	RT 3D Mode
<i>Anatomy/Region of Interest</i>											
Ophthalmic											
Fetal / Obstetrics	P ²	P ²	P ²		P ²	P ²	P ²	P ²	P ²	P ²	
Abdominal ^[1]	P ²	P ²	P ²		P ²	P ²	P ²	P ²	P ²	P ²	
Pediatric	P ²	P ²	P ²		P ²	P ²	P ²	P ²	P ²	P ²	
Small Organ ^[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac ^[3]											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)											
<i>Exam Type, Means of Access</i>											
Transcranial											
Transesophageal											
Transrectal											
Transvaginal											
Intraoperative ^[4]											
<i>Interventional Guidance</i>											
Intracardiac and Intraluminal											
Tissue Biopsy ^[5]	N	N	N		N	N	N	N	N	N	
Vascular Access (IV, PICC)											

N= new indication; P= previously cleared by FDA K121062; P¹ = previously cleared by FDA K150087; P²=previously cleared by FDA K160184; P³ = previously cleared by FDA K160277; P⁴ = previously cleared by FDA K160078; P⁵ = previously cleared by FDA K140318 by Biosense Webster, Inc.

Notes: [1] Abdominal includes GYN and Urological; [2] Small Organ includes breast, testes, thyroid; [3] Cardiac is Adult and Pediatric; [4] Intraoperative includes thoracic(cardiac) and vascular (PV); [5] Includes image guidance for freehand needle placement; [*]Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD; [**] Coded Pulse is for digitally encoded harmonics.

(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

GE Vivid iq with E8Cs-RS Transducer

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

Clinical Application	Mode of Operation										
	B	M	PW	CW	Color	Color M	PDI	Combined Modes*	Harmonic Imaging	Coded Pulse**	RT 3D Mode
<i>Anatomy/Region of Interest</i>											
Ophthalmic											
Fetal / Obstetrics	P ³	P ³	P ³		P ³	N	P ³	P ³	P ³	N	
Abdominal ^[1]	P ³	P ³	P ³		P ³	N	P ³	P ³	P ³	N	
Pediatric											
Small Organ ^[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac ^[3]											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)											
<i>Exam Type, Means of Access</i>											
Transcranial											
Transesophageal											
Transrectal	P ³	P ³	P ³		P ³	N	P ³	P ³	P ³	N	
Transvaginal	P ³	P ³	P ³		P ³	N	P ³	P ³	P ³	N	
Intraoperative ^[4]											
<i>Interventional Guidance</i>											
Intracardiac and Intraluminal											
Tissue Biopsy ^[5]	P ³	P ³	P ³		P ³	N	P ³	P ³	P ³	N	
Vascular Access (IV, PICC)											

N= new indication; P= previously cleared by FDA K121062; P¹ = previously cleared by FDA K150087; P²=previously cleared by FDA K160184; P³ = previously cleared by FDA K160277; P⁴ = previously cleared by FDA K160078; P⁵ = previously cleared by FDA K140318 by Biosense Webster, Inc.

Notes: [1] Abdominal includes GYN and Urological; [2] Small Organ includes breast, testes, thyroid; [3] Cardiac is Adult and Pediatric; [4] Intraoperative includes thoracic(cardiac) and vascular (PV); [5] Includes image guidance for freehand needle placement; [*]Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD; [**] Coded Pulse is for digitally encoded harmonics.

(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

GE Vivid iq with 8C-RS Transducer

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

Clinical Application	Mode of Operation										
	B	M	PW	CW	Color	Color M	PDI	Combined Modes*	Harmonic Imaging	Coded Pulse**	RT 3D Mode
<i>Anatomy/Region of Interest</i>											
Ophthalmic											
Fetal / Obstetrics											
Abdominal ^[1]	P	P	P		P	P	P	P	P	P	
Pediatric	P	P	P		P	P	P	P	P	P	
Small Organ ^[2]											
Neonatal Cephalic	P	P	P		P	P	P	P	P	P	
Adult Cephalic											
Cardiac ^[3]	P	P	P		P	P	P	P	P	P	
Peripheral Vascular	P	P	P		P	P	P	P	P	P	
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)											
<i>Exam Type, Means of Access</i>											
Transcranial											
Transesophageal											
Transrectal											
Transvaginal											
Intraoperative ^[4]											
<i>Interventional Guidance</i>											
Intracardiac and Intraluminal											
Tissue Biopsy ^[5]											
Vascular Access (IV, PICC)											

N= new indication; P= previously cleared by FDA K121062; P¹ = previously cleared by FDA K150087; P²=previously cleared by FDA K160184; P³ = previously cleared by FDA K160277; P⁴ = previously cleared by FDA K160078; P⁵ = previously cleared by FDA K140318 by Biosense Webster, Inc.

Notes: [1] Abdominal includes GYN and Urological; [2] Small Organ includes breast, testes, thyroid; [3] Cardiac is Adult and Pediatric; [4] Intraoperative includes thoracic(cardiac) and vascular (PV); [5] Includes image guidance for freehand needle placement; [*]Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD; [**] Coded Pulse is for digitally encoded harmonics.

(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)**



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: June 16, 2016

Submitter: GE Medical Systems Ultrasound and Primary Care Diagnostics
9900 Innovation Drive
Wauwatosa, WI 53226

Primary Contact Person: Tracey Ortiz
Regulatory Affairs Director
GE Healthcare
T:(262)676-6120
F:(414)918-8275

Secondary Contact Person: Nick Xu
Regulatory Affairs
GE Medical Systems (China) Co, Ltd.
T: +86 510 8527 8639
F: +86 510 8522 7347

Device: Trade Name: Vivid *iq*
Common/Usual Name: Diagnostic Ultrasound System
Classification Names: Class II
Ultrasonic Pulsed Doppler Imaging System. 21CFR 892.1550 90-
Product Code: IYN Ultrasonic Pulsed Echo Imaging System, 21CFR 892.1560,
90-IYO Diagnostic Ultrasound Transducer, 21 CFR 892.1570,
90-ITX

Primary Predicate Device: Vivid i and Vivid q (K121062)
Secondary Predicate
Device(s): Vivid E95 (K150087)
Voluson S10 (K160184)
LOGIQ F8 Expert (K160277)

Device Description: The Vivid *iq* is a high-performance compact ultrasound system designed for cardiovascular and shared services applications. It offers an innovative ergonomic design, superb image quality, advanced connectivity, productivity tools and advanced technology. Compatibility with the Vivid product family offers flexibility in lab configuration and upgrade opportunities.

Intended Use: The Vivid *iq* is a high-performance compact ultrasound system designed for cardiovascular and shared services applications. The indications of the product will include Fetal, OB, Abdominal, Pediatric, small Organ, Neonatal Cephalic, Adult Cephalic,



GE Healthcare

510(k) Premarket Notification Submission

Cardiac, Peripheral Vascular, Musculo-skeletal Conventional, Musculo-skeletal Superficial, Transcranial, Transrectal, Transvaginal, Transesophageal, Tissue biopsy, Intraoperative, IntraCardiac and Intraluminal.

Technology: The Vivid *iq* employs the same fundamental scientific technology as its predicate devices.

Determination of Substantial Equivalence: Comparison to Predicate Devices
The Vivid *iq* system is substantially equivalent to the predicate devices with regard to intended use, imaging capabilities, technological characteristics and safety and effectiveness.

- The systems are all intended for diagnostic ultrasound imaging and fluid flow analysis.
- The Vivid *iq* and its predicate Vivid *i* and Vivid *q* (K121062) have the same clinical indications for use except for tissue biopsy which was cleared in LOGIQ F8 Expert (K160277).
- The Vivid *iq* and its predicate Vivid *i* and Vivid *q* (K121062) have the same imaging modes except Real Time 3D mode which has been cleared in Vivid E95 (K150087).
- The Vivid *iq* and its predicate Vivid *i* and Vivid *q* (K121062) transducers are identical except for the M5Sc-RS, E8Cs-RS, L8-18i-RS, ML6-15-RS, C1-5-RS, 6VT-D, and SOUNDSTAR eco 8F (G version) probes.
- The 6VT-D and M5Sc-RS (equivalent to M5Sc-D with only a change in RS connector) probes are being added and were cleared on Vivid E95 (K150087).
- The E8Cs-RS and L8-18i-RS probes are being added and were cleared in LOGIQ F8 Expert (K160277).
- The ML6-15-RS and C1-5-RS are being added and were cleared in Voluson S10 (K160184).
- The SOUNDSTAR eco 8F (G version) is being added and was cleared in K140318 by Biosense Webster, Inc.
- The systems are manufactured with materials which have been evaluated and found to be safe for the intended use of the device.
- The systems have acoustic power levels which are below the applicable FDA limits.
- The Vivid *iq* and its predicate Vivid *i* and Vivid *q* (K121062) have similar capability in terms of performing



GE Healthcare

510(k) Premarket Notification Submission

measurements, capturing digital images, reviewing and reporting studies.

- The Vivid *iq* and its predicate Vivid *i* and Vivid *q* (K121062) have been designed in compliance with approved electrical and physical safety standards.
- The embedded operating system used is Windows 7 as it is in LOGIQ F8 Expert (K160277).

Summary of Non-Clinical Tests:

Vivid *iq* has been evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness as well as thermal, electrical, electromagnetic, and mechanical safety, and has been found to comply with applicable medical device safety standards.

The Vivid *iq* complies with voluntary standards:

- AAMI/ANSI ES60601-1, Medical Electrical Equipment – Part 1: General Requirements for Safety, 2005
- IEC60601-1-2, Medical Electrical Equipment – Part 1-2: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility Requirements and Tests, 2014
- IEC60601-2-37, Medical Electrical Equipment – Part 2-37: Particular Requirements for the Safety of Ultrasonic Medical Diagnostic and Monitoring Equipment, 2015
- NEMA UD 3, Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment, 2004
- ISO10993-1, Biological Evaluation of Medical Devices- Part 1: Evaluation and Testing- Third Edition, 2009
- NEMA UD 2, Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment, 2004
- ISO14971, Application of risk management to medical devices, 2007
- NEMA, Digital Imaging and Communications in Medicine (DICOM) Set. (Radiology), 2011

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

- Risk Analysis
- Requirements Reviews
- Design Reviews



GE Healthcare

510(k) Premarket Notification Submission

- 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 are biocompatible.

Summary of Clinical Tests:

The subject of this premarket submission, Vivid *iq*, did not require clinical studies to support substantial equivalence.

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