K133034
Page 1 of 4

GE Healthcare
510(k) Premarket Notification Submission

510(k) Summary

JAN 31 2014

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

Date:	December 5, 2013
Submitter:	GE Healthcare 9900 Innovation Dr Wauwatosa, WI 53226
Primary Contact Person:	Bryan Behn Regulatory Affairs Manager GE Healthcare T:(414)721-4214 F:(414)918-8275
Secondary Contact Person:	Jiawei ZHANG Regulatory Affairs GE Healthcare T: +86 510 8527 8259 F: +86 510 8522 7347
Device: Trade Name:	LOGIQ F SERIES
Common/Usual Name:	LOGIQ F8, LOGIQ F6, LOGIQ F5, LOGIQ F3
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):	K122387 GE Voluson P8 K131527 GE LOGIQ S8 K113690 LOGIQ e/i, Vivid e
Device Description:	The LOGIQ F Series is the full featured general purpose diagnostic ultrasound system which consists of a mobile console (Approximately 72 cm wide, 80 cm deep and145 cm high) that provides digital acquisition, processing and display capability. The user interface includes a computer keyboard, color LCD image display and touch panel.

Main Differences Between Models

Product name	LOGIQ F8	LOGIQ F6	LOGIQ F5	LOGIQ F3
Imaging	Color	Color	Color	Black & White
LCD	19'LCD	17'LCD or 19'LCD	17'LCD or 19'LCD	17'LCD

Intended Use: The LOGIQ F SERIES is a general purposed ultrasound imaging and analysis systems providing digital acquisition, processing and display capability, clinical applications including: Abdominal, Obstetrical, Gynecological, Small parts, Vascular/Peripheral Vascular, Transcranial, Pediatric, Musculoskeletal, Urological, Cardiac, Transvaginal

Technology: The LOGIQ F SERIES employs the same fundamental scientific technology as its predicate devices.

Determination of Substantial Equivalence:

Comparison to Predicate Devices

The LOGIQ F Series 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 LOGIQ F Series and predicate systems have similar clinical intended use and similar imaging modes.
- All the transducers used on LOGIQ F Series have been cleared on Voluson P8 (K122387) except 8C-RS and L6-12-RS.
- 8C-RS has been cleared on LOGIQ e/i, Vivid e (K113690).
- L6-12-RS is a new transducer equivalent to the predicate L8-18-RS on the LOGIQ e/i, Vivid e (K113690).
- 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.
- Elastography, Tissue Velocity Imaging (TVI)/Tissue Velocity Doppler (TVD), Auto IMT and Quantitative

Analysis have been previously cleared on the LOGIQ S8 (K131527).

The LOGIQ F Series and predicate systems have been designed in compliance with approved electrical and physical safety standards.

Summary of Non-Clinical Tests:

The LOGIQ F SERIES 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 LOGIQ F SERIES complies with voluntary standards:

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

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

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Testing on unit level (Module verification)
- Integration testing (System verification)
- 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, LOGIQ F Series, did not require clinical studies to support substantial equivalence.

Conclusion: GE Healthcare considers the LOGIQ F Series to be as safe, as effective, and performance is substantially equivalent to the predicate device(s).

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510(k) Number: **K133034/S002 – GE Healthcare**

Digital Signature Concurrence Table	
Reviewer Sign-Off	Shahram Vaezy January 30, 2014
Branch Chief Sign-Off	Robert Ochs January 30, 2014
Division Sign-Off	Sean M. Boyd -S 2014.01.31 15:52:42 -05'00'

QC: FMEba:fme:1/30/2014

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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

January 31, 2014

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

Re: K133034
Trade/Device Name: LOGIQ F Series
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX
Dated: January 22, 2014
Received: January 23, 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 LOGIQ F Series, as described in your premarket notification:

Transducer Model Number

4C-RS	8C-RS
3Sc-RS	L6-12-RS
E8C-RS	RAB2-6-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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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

510(k) Number (if known): K133034

Device Name: LOGIQ F Series

Indications for Use:

The LOGIQ F SERIES are general purposed ultrasound imaging and analysis systems providing digital acquisition, processing and display capability, clinical applications including: Abdominal, Obstetrical, Gynecological, Small parts, Vascular/Peripheral Vascular, Transcranial, Pediatric, Musculoskeletal, Urological, Cardiac, Transvaginal

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

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

(Division Sign-Off)
Division of Radiological Health
Office of In Vitro Diagnostics and Radiological Health
510(k) K133034

Diagnostic Ultrasound Indications for Use Form

LOGIQ F8, F6, F5 Ultrasound Systems

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		[5]
Abdominal[1]	N		N		N		N	N	N		[5]
Pediatric	N	N	N	N	N	N	N	N	N		
Small Organ (specify)[2]	N		N		N		N	N	N		[6]
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]	N	N	N	N	N	N	N	N	N		
Peripheral Vascular	N		N		N		N	N	N		
Musculo-skeletal Conventional	N		N		N		N	N	N		
Musculo-skeletal Superficial	N		N		N		N	N	N		
Thoracic/Pleural (specify)											
Other (specify)											
Exam Type, Means of Access											
Transcranial	N	N			N		N	N	N		
Transorbital											
Transesophageal											
Transrectal											
Transvaginal	N	N			N		N	N	N		
Intraoperative (specify)											
Intraoperative Neurological											
Laparoscopic											
Interventional Guidance											
Tissue Biopsy/Fluid Drainage[4]	N	N	N	N	N	N	N	N	N		
Vascular Access (IV, PICC)											
Nonvascular (specify)											

N = new indication; P = previously cleared by FDA

Notes: [1] Abdominal includes GYN and Urological;
[2] Small Organ includes breast, testes, thyroid;
[3] Cardiac is Adult and Pediatric;
[4] Interventional Guidance Tissue Biopsy is 2D biopsy guide:
[5] 3D/4D Imaging Mode
[6] Elastography imaging- Elasticity
[*] 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

LOGIQ F3 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		
Abdominal[1]	N		N					N	N		
Pediatric	N	N	N	N				N	N		
Small Organ (specify)[2]	N		N					N	N		
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]	N	N	N	N				N	N		
Peripheral Vascular	N		N					N	N		
Musculo-skeletal Conventional	N		N					N	N		
Musculo-skeletal Superficial	N		N					N	N		
Thoracic/Pleural (specify)											
Other (specify)											
Exam Type, Means of Access											
Transcranial	N	N						N	N		
Transorbital											
Transesophageal											
Transrectal											
Transvaginal	N	N						N	N		
Intraoperative (specify)											
Intraoperative Neurological											
Laparoscopic											
Interventional Guidance											
Tissue Biopsy/Fluid Drainage[4]	N	N	N	N				N	N		
Vascular Access (IV, PICC)											
Nonvascular (specify)											

N = new indication: P = previously cleared by FDA

Notes: [1] Abdominal includes GYN and Urological:
[2] Small Organ includes breast, testes, thyroid:
[3] Cardiac is Adult and Pediatric:
[4] Interventional Guidance Tissue Biopsy is 2D biopsy guide:
[*] Combined modes are color/power Doppler with B-mode

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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

LOGIQ F Series 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	
Pediatric	P		P		P		P	P	P	P	
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											
Transvaginal											
Intraoperative (specify)											
Intraoperative Neurological											
Laparoscopic											
Interventional Guidance											
Tissue Biopsy/Fluid Drainage[4]	N	N			N		N	N	N	N	
Vascular Access (IV, PICC)											
Nonvascular (specify)											

N = new indication; P = previously cleared by FDA (K122387)

Notes: [1] Abdominal includes GYN and Urological;
[2] Small Organ includes breast, testes, thyroid;
[3] Cardiac is Adult and Pediatric;
[4] Interventional Guidance Tissue Biopsy is 2D biopsy guide
[*] 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

LOGIQ F Series 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]	P		P		P		P	P	P		
Pediatric	P	P	P	P	P	P	P	P	P		
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											
Transrectal											
Transvaginal											
Intraoperative (specify)											
Intraoperative Neurological											
Laparoscopic											
Interventional Guidance											
Tissue Biopsy/Fluid Drainage											
Vascular Access (IV, PICC)											
Nonvascular (specify)											

N = new indication; P = previously cleared by FDA(K113690)

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

LOGIQ F Series 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		
Pediatric	P	P	P		P	P	P	P	P		
Small Organ (specify)[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]	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	P	P	P		P	P	P	P	P		
Transorbital											
Transesophageal											
Transrectal											
Transvaginal											
Intraoperative (specify)											
Intracardiac											
Laparoscopic											
Interventional Guidance											
Tissue Biopsy/Fluid Drainage[4]	N	N	N		N	N	N	N	N		
Vascular Access (IV, PICC)											
Nonvascular (specify)											

N = new indication: P = previously cleared by FDA(K122387)

Notes: [1] Abdominal includes GYN and Urological
[2] Small Organ includes breast, testes, thyroid
[3] Cardiac is Adult and Pediatric
[4] Interventional Guidance Tissue Biopsy is 2D biopsy guide;
[*] 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

LOGIQ F Series 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]											
Pediatric	N		N		N		N	N	N		
Small Organ (specify)[2]	N		N		N		N	N	N		[6]
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]											
Peripheral Vascular	N		N		N		N	N	N		
Musculo-skeletal Conventional	N		N		N		N	N	N		
Musculo-skeletal Superficial	N		N		N		N	N	N		
Thoracic/Pleural (specify)											
Other (specify)											
Exam Type, Means of Access											
Transcranial											
Transorbital											
Transesophageal											
Transrectal											
Transvaginal											
Intraoperative (specify)											
Intraoperative Neurological											
Laparoscopic											
Interventional Guidance											
Tissue Biopsy/Fluid Drainage[4]	N		N		N		N	N	N		
Vascular Access (IV, PICC)											
Nonvascular (specify)											

N = new indication; P = previously cleared by FDA

Notes: [1] Abdominal includes GYN and Urological;
[2] Small Organ includes breast, testes, thyroid;
[3] Cardiac is Adult and Pediatric;
[4] Interventional Guidance Tissue Biopsy is 2D biopsy guide
[5] 3D/4D Imaging Mode
[6] Elastography imaging- Elasticity
[*] Combined modes are B/M, B/Color M, B/PWD, B/Color/PWD, B/PWD

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

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

LOGIQ F Series 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		
Abdominal[1]											
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											
Transvaginal	P	P	P		P		P	P	P		
Intraoperative (specify)											
Intraoperative Neurological											
Laparoscopic											
Interventional Guidance											
Tissue Biopsy/Fluid Drainage[4]	N	N	N		N		N	N	N		
Vascular Access (IV, PICC)											
Nonvascular (specify)											

N = new indication; P = previously cleared by FDA(K122387)

Notes: [1] Abdominal includes GYN and Urological;
[2] Small Organ includes breast, testes, thyroid;
[3] Cardiac is Adult and Pediatric;
[4] Interventional Guidance Tissue Biopsy is 2D biopsy guide;
[*] 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

LOGIQ F Series with RAB2-6-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		[5]
Abdominal[1]	P		P		P		P	P	P		[5]
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											
Transvaginal											
Intraoperative (specify)											
Intraoperative Neurological											
Laparoscopic											
Interventional Guidance											
Tissue Biopsy/Fluid Drainage[4]	N	N	N		N	N	N	N	N		[5]
Vascular Access (IV, PICC)											
Nonvascular (specify)											

N = new indication: P = previously cleared by FDA (K122387)

Notes: [1] Abdominal includes GYN and Urological
[2] Small Organ includes breast, testes, thyroid
[3] Cardiac is Adult and Pediatric
[4] Interventional Guidance Tissue Biopsy is 2D biopsy guide:
[5] 3D/4D Imaging Mode
[6] Elastography imaging- Elasticity
[*] Combined modes are B/M, B/Color M, B/PWD, B/Color/PWD, B/PWD

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

Prescription Use (Per 21 CFR 801.109)