K102997

510 (k) Summary for the SonixTABLET Ultrasound Scanner

DEC 21 2010

This summary of safety and effectiveness is provided as part of this Premarket Notification in compliance with the Safe Medical Devices Act of 2009 revision to 21 CFR, Part 807.92, Content and format of a 510(k) summary.

1.0 Submitter Information

1.1 Submitter

Ultrasonix Medical Corporation
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Richmond, British Columbia
Canada V6V 2K9
(t) 604-279-8550
(f) 604-279-8559

1.2 Contact

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(t) 604-279-8550 x 152
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(e) chas.yu@ultrasonix.com

1.3 Date Prepared

July 31, 2010

2.0 Device Name

2.1 Common Name

Ultrasound Imaging System

2.2 Proprietary Name

SonixTABLET Ultrasound Scanner

2.3 Classification Name

	FR Number	Product Code
Ultrasonic Pulsed Doppler Imaging System	892.1550	90-IYN
Ultrasonic Pulsed Echo Imaging System	892.1560	90-IYO
Diagnostic Ultrasound Transducer	892.1570	90-ITX

2.4 Classification

Class II

2.5 Predicate Device:

Sonix Ultrasound Scanner (K093462)
Sonix TOUCH Ultrasound Scanner (K083095)
SONIX MDP Ultrasound Scanner (K080935)

2.6 Reason for submission:

Name change request

N/A

New product clearance for:

SonixTABLET Ultrasound Scanner

Supporting Transducers:

- 4DC7-3/40
- 4DEC9-5/10
- 4DL14-5/38
- BPL9-5/55
- BPC8-4/10
- C5-2/60
- C5-2/60 GPS
- C7-3/50
- MC9-4/12
- EC9-5/10
- EC9-5/10 GPS
- HST15-8/20
- L9-4/38
- L14-5/38
- L14-5/38 GPS
- L14-5W/60
- PA7-4/12
- SA4-2/24
- mTEE8-3/5

2.7 Device description

The SonixTABLET Ultrasound Scanner is a new multi-purpose mobile, software controlled diagnostic ultrasound system with on-screen thermal and mechanical indices related to potential bio-effect mechanisms. Its function is to acquire primary or secondary harmonic ultrasound echo data and display it in B-Mode, M-Mode, Pulsed (PW) Doppler Mode, Continuous (CW) Doppler Mode, Color Doppler Mode, Amplitude Doppler Mode, a combination of modes, or Harmonic imaging on a Flat Panel Display. The user interface includes specialized controls, a minimized computer keyboard, and touch panel on an ergonomic console.

The system has an optional electrocardiography (ECG) display feature and support for a 3-lead ECG cable assembly. The systems provide measurement capabilities for anatomical structures and fetal biometry that provide information used for clinical diagnostic purposes. The system has a PW and CW audio output feature and cine review, image zoom, labeling, biopsy, measurements and calculations, image storage and review, printing, and recording capabilities. The systems include a Digital Imaging and Communications (DICOM) module which enables storage.

The system is designed for use in linear, convex and phased array scanning modes, and supports linear, convex, microconvex and phased array probes.

The biopsy kits are accessories to the SonixTABLET Ultrasound Scanner. These accessories are made up of a polymeric bracket. There are features on the bracket that prevent the bracket from being oriented incorrectly when attached to the transducer. The brackets are not sterile and will be covered with a sterile sheath prior to use. These brackets are designed to accept and retain the needle guides in a mechanically secure way through the medium of the sterile sheath. The brackets are reusable. The needle guide is a separate sterile polymeric part that attaches to the bracket through a sterile sheath. The needle guides will support various sized needles. The needle guides are sold in sterile kits that contain multiple needle guides, sterile sheaths, ultrasound transmission gel, and bands.

Frequency Range	2-40MHz
Transducer types	Linear array Curved array TEE array Intracavity array Phased array

The SonixTABLET Ultrasound Scanner is designed to comply with the following standards and the system follows Track 3.

Reference Number	Title	FDA Recognition Number
IEC 60601-1	IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995.	5-4
IEC 60601-1-2	IEC 60601-1-2, Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral standard: Electromagnetic Compatibility - Requirements and Tests (Edition 2:2001 with Amendment 1:2004; Edition 2.1 (Edition 2:2001 consolidated with Amendment 1:2004)).	5-34
IEC 60601-2-37	IEC 60601-2-37 (2004) (2005) Amendment 2, Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment.	12-198
AIUM AOL	Acoustic Output Labeling Standard for Diagnostic Ultrasound Equipment Revision 1 - A standard for How Manufacturers Should Specify Acoustic Output Data	12-193
AIUM RTD1-2004	Standard for Real - Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment Revision 1	12-140

3.0 Summary of Intended Uses

The SonixTABLET Ultrasound Imaging System is intended for the following applications: Abdominal, Cardiac, Intraoperative Neurological, Fetal, Pediatric, Small Parts, Neonatal / Adult Cephalic, OB/GYN, Transesophageal, Transrectal, Transvaginal, Peripheral Vascular, Musculoskeletal conventional, Musculoskeletal superficial, Pelvic, Nerve block, Vascular Access, Transcranial

The system also provides the ability to measure anatomical structures {fetal, abdominal, pediatric, small organ, cardiac, transrectal, transvaginal, peripheral vessel, musculo-skeletal} and calculation packages that provide information to the clinician that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes.

4.0 Comparison to Predicate Device

The SonixTABLET Ultrasound Scanner is substantially equivalent to the predicate devices listed below with respect to intended use/indications for use, principles of operation and technological characteristics.

The SonixTABLET Ultrasound Scanner includes a digital beamformer that is similar in function to the predicate devices beamformer. It allows transmitting and receiving signals through the ultrasound transducers. The ultrasound transducers are similar to the ones used on predicate devices.

The backend processing is also similar to the predicate devices and yields an ultrasound image in realtime for diagnosis purposes.

Sonix Ultrasound Scanner (K093462)
Sonix TOUCH Ultrasound Scanner (K083095)
Sonix MDP Ultrasound Scanner (K080935)

5.0 Technological characteristics

The technological characteristics are substantially similar to that of the predicates. The device operates identically to the predicate devices in that piezoelectric material in the transducer is used as an ultrasound source to transmit sound waves into the body. Sound waves are reflected back to the transducer and converted to electrical signals that are processed and displayed as 2D or M-mode images. Doppler shift caused by blood flow is displayed as Color Flow, or as spectrum analysis. The modes of this device (2D, PW Doppler, Color Flow Mapping Doppler, Power Doppler, Continuous Wave Doppler) are the same as the predicate devices identified in item 2.5. Transducer patient contact materials are biocompatible.

The beam forming architecture is very similar to that of the predicate devices. The receiving and processing hardware is similar but innovative in that it is a programmable system made of 2 building blocks, which can be reconfigured to operate the system in any imaging mode.

The parameters used to adjust image quality are the same as that seen in the predicates. This includes the use of TGC gain, depth control, base control and angling, among others.

6.0 Safety considerations

As track 3 ultrasound device, the SonixTABLET Ultrasound Scanner is designed to comply with the "Standard For Real Time Display Of Thermal And Mechanical Acoustic Output Indices On Diagnostic Ultrasound Equipment (2004)" published by the National Electrical Manufacturers Association as UD-3.

With respect to limits on acoustic outputs, the SonixTABLET Ultrasound Scanner complies with the guideline limits set in the September 9, 2008 revision of 510(k) Diagnostic Ultrasound Guidance.

With regard to general safety, the SonixTABLET Ultrasound Scanner is designed to comply with IEC 60601-1 (1988) Medical Electrical Equipment, Part 1: General Requirements for Safety, and IEC 60601-2-37: Particular Requirements For The Safety Of Ultrasonic Medical Diagnostic And Monitoring Equipment.

The devices' acoustic output limits are:

I_{SPTA} (d)	720mW/cm^2
TIS/TIB/TIC	0.1 – 4.0 (Range)
Mechanical Index (MI)	1.9 (Maximum)
I_{SPPA} (d)	0 – 700W/cm^2 (Range)

The limits are the same as predicate Track 3 devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

DEC 21 2010

Ultrasonix Medical Corporation
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K102997
Trade/Device Name: SonixTABLET Ultrasound Scanner
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, and ITX
Dated: December 3, 2010
Received: December 6, 2010

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the SonixTABLET Ultrasound Scanner, as described in your premarket notification:

Transducer Model Number

4DC7-3/40 Motorized Convex Radius
4DEC9-5/10 Motorized Microconvex Endocavity Radius
4DL14-5/38 Motorized Linear
BPL9-5/55 Linear Biplane
BPC8-4/10 Microconvex Endocavity Biplane
C5-2/60 and C5-2/60 GPS Convex
C7-3/50 Convex
MC9-4/12 Microconvex
EC9-5/10 AND EC9-5/10 GPS Microconvex Endocavity Radius

HST15-8/20 Linear
L9-4/38 Linear
L14-5/38 AND L14-5/38 GPS Linear
L14-5W60 Wide Linear
PA7-4/12 Phased Array
SA4-2/24 Phased Array
mTEE8-3/5 Transesophageal Phased Array Radius

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Shahram Vaezy at (301) 796-6242.

Sincerely yours,

David G. Brown, Ph.D.
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure(s)

Indications for Use

510(k) Number (if known):
Device Name: SonixTABLET Ultrasound Scanner
Indications For Use:

The SonixTABLET Ultrasound Scanner is intended for the following applications: Abdominal, Cardiac, Intraoperative Neurological, Fetal, Pediatric, Small Parts, Neonatal/ Adult Cephalic, OB/GYN, Transesophageal, Transrectal,Transvaginal, Peripheral Vascular, Musculoskeletal conventional, Musculoskeletal superficial, Pelvic, Nerve Block, Vascular Access, Transcranial.

The system also provides the ability to measure anatomical structures {fetal, abdominal, pediatric, small organ, cardiac, transrectal, transvaginal, peripheral vessel, musculoskeletal} and provides calculation packages that provide information to the clinician that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes.

Prescription Use __X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, ~~Office of Device Evaluation (ODE)~~ ODLVD

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

510K K102997

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

SONIXTABLET ULTRASOUND SCANNER

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

Clinical Application	Mode of Operation							
	B	M	PW Doppler	CW Doppler	Color Doppler	Power Doppler	Combined Modes[12]	Other [Notes]
Ophthalmic								
Fetal	N	N	N		N	N	N	N [3-8,11]
Abdominal	N	N	N	N	N	N	N	N [3-8,11]
Intraoperative[1]								
Intraoperative Neurological	N	N	N		N	N	N	N [3-6,8]
Pediatric	N	N	N	N	N	N	N	N [3-8,11]
Small Organ[2]	N	N	N		N	N	N	N [3-8,11]
Neonatal Cephalic	N	N	N		N	N	N	N [3-6,8,11]
Adult Cephalic	N	N	N	N	N	N	N	N [3-6,8,11]
Cardiac	N	N	N	N	N	N	N	N [3-6,8,11]
Transesophageal	N	N	N	N	N	N	N	
Transrectal	N	N	N	N	N	N	N	N [3-8,11]
Transvaginal	N	N	N		N	N	N	N [3-8,11]
Transurethral								
Transcranial	N	N	N	N	N	N	N	N [3-6,8]
Peripheral Vascular	N	N	N		N	N	N	N [3-6,8,10,11]
Laparoscopic								
MSK Conventional	N	N	N		N	N	N	N [3-8,11]
MSK Superficial	N	N	N		N	N	N	N [3-8,11]
Vascular Access	N	N	N		N	N	N	N [3-8,10,11]
Nerve Block	N	N	N		N	N	N	N [3-6,8-9,11]
Other								

N = New indication

Notes:

1. Abdominal organs and vascular
2. Breast, Thyroid, Testicle
3. Elastography
4. Panoramic Imaging
5. Compound Imaging
6. Freehand 3D Imaging
7. Live 3D/4D Imaging
8. Imaging for guidance of biopsy
9. Imaging for guidance of nerve block injections
10. Imaging for guidance of central or peripheral lines
11. Volume Navigation/Image Fusion/SonixGPS™ (available only with the GPS transducers)
12. B/M, B/PW Doppler or CW Doppler, B/C/PW Doppler (Triplex) or CW Doppler (Triplex CW), B/Power Doppler/PW Doppler or CW Doppler, Simultaneous Color Doppler or Power Doppler.

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DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

4DC7-3/40 Motorized Convex Radius Transducer

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

Clinical Application	Mode of Operation							
	B	M	PW Doppler	CW Doppler	Color Doppler	Power Doppler	Combined Modes[12]	Other [Notes]
Ophthalmic								
Fetal	P	P	P		P	P	P	P [3-8]
Abdominal	P	P	P		P	P	P	P [3-8]
Intraoperative[1]								
Intraoperative Neurological								
Pediatric	P	P	P		P	P	P	P [3-8]
Small Organ[2]	P	P	P		P	P	P	P [3-8]
Neonatal Cephalic								
Adult Cephalic								
Cardiac								
Transesophageal								
Transrectal								
Transvaginal								
Transurethral								
Transcranial								
Peripheral Vascular								
Laparoscopic								
MSK Conventional	P	P	P		P	P	P	P [3-8]
MSK Superficial	P	P	P		P	P	P	P [3-8]
Vascular Access								
Nerve Block								
Other								

N = New indication; P = Previously cleared under K093462

Notes:

1. Abdominal organs and vascular
2. Breast, Thyroid, Testicle
3. Elastography
4. Panoramic Imaging
5. Compound Imaging
6. Freehand 3D Imaging
7. Live 3D/4D Imaging
8. Imaging for guidance of biopsy
9. Imaging for guidance of nerve block injections
10. Imaging for guidance of central or peripheral lines
11. Volume Navigation/Image Fusion/SonixGPS™ (available only with the GPS transducers)
12. B/M, B/PW Doppler or CW Doppler, B/C/PW Doppler (Triplex) or CW Doppler (Triplex CW), B/Power Doppler/PW Doppler or CW Doppler, Simultaneous Color Doppler or Power Doppler.

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DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

4DEC9-5/10 Motorized Microconvex Endocavity Radius Transducer

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

Clinical Application	Mode of Operation							
	B	M	PW Doppler	CW Doppler	Color Doppler	Power Doppler	Combined Modes[12]	Other [Notes]
Ophthalmic								
Fetal								
Abdominal								
Intraoperative[1]								
Intraoperative Neurological								
Pediatric								
Small Organ[2]								
Neonatal Cephalic								
Adult Cephalic								
Cardiac								
Transesophageal								
Transrectal	P	P	P		P	P	P	P [3-8]
Transvaginal	P	P	P		P	P	P	P [3-8]
Transurethral								
Transcranial								
Peripheral Vascular								
Laparoscopic								
MSK Conventional								
MSK Superficial								
Vascular Access								
Nerve Block								
Other								

N = New indication; P = Previously cleared under K093462

Notes:

1. Abdominal organs and vascular
2. Breast, Thyroid, Testicle
3. Elastography
4. Panoramic Imaging
5. Compound Imaging
6. Freehand 3D Imaging
7. Live 3D/4D Imaging
8. Imaging for guidance of biopsy
9. Imaging for guidance of nerve block injections
10. Imaging for guidance of central or peripheral lines
11. Volume Navigation/Image Fusion/SonixGPS™ (available only with the GPS transducer)
12. B/M, B/PW Doppler or CW Doppler, B/C/PW Doppler (Triplex) or CW Doppler (Triplex CW), B/Power Doppler/PW Doppler or CW Doppler, Simultaneous Color Doppler or Power Doppler.

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DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

4DL14-5/38 Motorized Linear Transducer

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

Clinical Application	Mode of Operation							
	B	M	PW Doppler	CW Doppler	Color Doppler	Power Doppler	Combined Modes[12]	Other [Notes]
Ophthalmic								
Fetal								
Abdominal	P	P	P		P	P	P	P [3-8]
Intraoperative[1]								
Intraoperative Neurological								
Pediatric	P	P	P		P	P	P	P [3-8]
Small Organ[2]	P	P	P		P	P	P	P [3-8]
Neonatal Cephalic								
Adult Cephalic								
Cardiac								
Transesophageal								
Transrectal								
Transvaginal								
Transurethral								
Transcranial								
Peripheral Vascular								
Laparoscopic								
MSK Conventional	P	P	P		P	P	P	P [3-8]
MSK Superficial	P	P	P		P	P	P	P [3-8]
Vascular Access	P	P	P		P	P	P	P [3-8,10]
Nerve Block	P	P	P		P	P	P	P [3-9]
Other								

N = New indication; P = Previously cleared under K093462

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Notes:

1. Abdominal organs and vascular
2. Breast, Thyroid, Testicle
3. Elastography
4. Panoramic Imaging
5. Compound Imaging
6. Freehand 3D Imaging
7. Live 3D/4D Imaging
8. Imaging for guidance of biopsy
9. Imaging for guidance of nerve block injections
10. Imaging for guidance of central or peripheral lines
11. Volume Navigation/Image Fusion/SonixGPS™ (available only with the GPS transducer)
12. B/M, B/PW Doppler or CW Doppler, B/C/PW Doppler (Triplex) or CW Doppler (Triplex CW), B/Power Doppler/PW Doppler or CW Doppler, Simultaneous Color Doppler or Power Doppler.

Prescription Use Only

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

BPL9-5/55 Linear Endocavity Biplane Transducer

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

Clinical Application	Mode of Operation							
	B	M	PW Doppler	CW Doppler	Color Doppler	Power Doppler	Combined Modes[12]	Other [Notes]
Ophthalmic								
Fetal								
Abdominal								
Intraoperative[1]								
Intraoperative Neurological								
Pediatric								
Small Organ[2]								
Neonatal Cephalic								
Adult Cephalic								
Cardiac								
Transesophageal								
Transrectal	P	P	P	P	P	P	P	P [3-6,8]
Transvaginal								
Transurethral								
Transcranial								
Peripheral Vascular								
Laparoscopic								
MSK Conventional								
MSK Superficial								
Vascular Access								
Nerve Block								
Other								

N = New indication; P = Previously cleared under K093462

Notes:

1. Abdominal organs and vascular
2. Breast, Thyroid, Testicle
3. Elastography
4. Panoramic Imaging
5. Compound Imaging
6. Freehand 3D Imaging
7. Live 3D/4D Imaging
8. Imaging for guidance of biopsy
9. Imaging for guidance of nerve block injections
10. Imaging for guidance of central or peripheral lines
11. Volume Navigation/Image Fusion/SonixGPS™ (available only with the GPS transducer)
12. B/M, B/PW Doppler or CW Doppler, B/C/PW Doppler (Triplex) or CW Doppler (Triplex CW), B/Power Doppler/PW Doppler or CW Doppler, Simultaneous Color Doppler or Power Doppler.

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DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

BPC8-4/10 Microconvex Endocavity Biplane Transducer

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

Clinical Application	Mode of Operation							
	B	M	PW Doppler	CW Doppler	Color Doppler	Power Doppler	Combined Modes[12]	Other [Notes]
Ophthalmic								
Fetal								
Abdominal								
Intraoperative[1]								
Intraoperative Neurological								
Pediatric								
Small Organ[2]								
Neonatal Cephalic								
Adult Cephalic								
Cardiac								
Transesophageal								
Transrectal	P	P	P	P	P	P	P	P [3-6,8]
Transvaginal								
Transurethral								
Transcranial								
Peripheral Vascular								
Laparoscopic								
MSK Conventional								
MSK Superficial								
Vascular Access								
Nerve Block								
Other								

N = New indication; P = Previously cleared under K093462

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Notes:

1. Abdominal organs and vascular
2. Breast, Thyroid, Testicle
3. Elastography
4. Panoramic Imaging
5. Compound Imaging
6. Freehand 3D Imaging
7. Live 3D/4D Imaging
8. Imaging for guidance of biopsy
9. Imaging for guidance of nerve block injections
10. Imaging for guidance of central or peripheral lines
11. Volume Navigation/Image Fusion/SonixGPS™ (available only with the GPS transducer)
12. B/M, B/PW Doppler or CW Doppler, B/C/PW Doppler (Triplex) or CW Doppler (Triplex CW), B/Power Doppler/PW Doppler or CW Doppler, Simultaneous Color Doppler or Power Doppler.

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DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

C5-2/60 and C5-2/60 GPS Convex Transducers

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

Clinical Application	Mode of Operation							
	B	M	PW Doppler	CW Doppler	Color Doppler	Power Doppler	Combined Modes[12]	Other [Notes]
Ophthalmic								
Fetal	P	P	P		P	P	P	P [3-6,8,11]
Abdominal	P	P	P		P	P	P	P [3-6,8,11]
Intraoperative[1]								
Intraoperative Neurological								
Pediatric	P	P	P		P	P	P	P [3-6,8,11]
Small Organ[2]	P	P	P		P	P	P	P [3-6,8,11]
Neonatal Cephalic								
Adult Cephalic								
Cardiac	P	P	P		P	P	P	P [3-6,8,11]
Transesophageal								
Transrectal								
Transvaginal								
Transurethral								
Transcranial								
Peripheral Vascular	P	P	P		P	P	P	P [3-6,8,11]
Laparoscopic								
MSK Conventional	P	P	P		P	P	P	P [3-6,8,11]
MSK Superficial	P	P	P		P	P	P	P [3-6,8,11]
Vascular Access								
Nerve Block								
Other								

N = New indication; P = Previously cleared under K093462

Notes:

1. Abdominal organs and vascular
2. Breast, Thyroid, Testicle
3. Elastography
4. Panoramic Imaging
5. Compound Imaging
6. Freehand 3D Imaging
7. Live 3D/4D Imaging
8. Imaging for guidance of biopsy
9. Imaging for guidance of nerve block injections
10. Imaging for guidance of central or peripheral lines
11. Volume Navigation/Image Fusion/SonixGPS™ (available only with the GPS transducer)
12. B/M, B/PW Doppler or CW Doppler, B/C/PW Doppler (Triplex) or CW Doppler (Triplex CW), B/Power Doppler/PW Doppler or CW Doppler, Simultaneous Color Doppler or Power Doppler.

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DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

C7-3/50 Convex Transducer

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

Clinical Application	Mode of Operation							
	B	M	PW Doppler	CW Doppler	Color Doppler	Power Doppler	Combined Modes[12]	Other [Notes]
Ophthalmic								
Fetal	P	P	P		P	P	P	P [3-6,8]
Abdominal	P	P	P		P	P	P	P [3-6,8]
Intraoperative[1]								
Intraoperative Neurological								
Pediatric	P	P	P		P	P	P	P [3-6,8]
Small Organ[2]	P	P	P		P	P	P	P [3-6,8]
Neonatal Cephalic								
Adult Cephalic								
Cardiac	P	P	P		P	P	P	P [3-6,8]
Transesophageal								
Transrectal								
Transvaginal								
Transurethral								
Transcranial								
Peripheral Vascular	P	P	P		P	P	P	P [3-6,8]
Laparoscopic								
MSK Conventional	P	P	P		P	P	P	P [3-6,8]
MSK Superficial	P	P	P		P	P	P	P [3-6,8]
Vascular Access								
Nerve Block								
Other								

N = New indication; P = Previously cleared under K093462

Notes:

1. Abdominal organs and vascular
2. Breast, Thyroid, Testicle
3. Elastography
4. Panoramic Imaging
5. Compound Imaging
6. Freehand 3D Imaging
7. Live 3D/4D Imaging
8. Imaging for guidance of biopsy
9. Imaging for guidance of nerve block injections
10. Imaging for guidance of central or peripheral lines
11. Volume Navigation/Image Fusion/SonixGPS™ (available only with the GPS transducer)
12. B/M, B/PW Doppler or CW Doppler, B/C/PW Doppler (Triplex) or CW Doppler (Triplex CW), B/Power Doppler/PW Doppler or CW Doppler, Simultaneous Color Doppler or Power Doppler.

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DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

MC9-4/12 Microconvex Transducer

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

Clinical Application	Mode of Operation							
	B	M	PW Doppler	CW Doppler	Color Doppler	Power Doppler	Combined Modes[12]	Other [Notes]
Ophthalmic								
Fetal								
Abdominal	P	P	P		P	P	P	P [3-6,8]
Intraoperative[1]								
Intraoperative Neurological								
Pediatric	P	P	P		P	P	P	P [3-6,8]
Small Organ[2]	P	P	P		P	P	P	P [3-6,8]
Neonatal Cephalic	P	P	P		P	P	P	P [3-6,8]
Adult Cephalic	P	P	P		P	P	P	P [3-6,8]
Cardiac								
Transesophageal								
Transrectal								
Transvaginal								
Transurethral								
Transcranial	P	P	P		P	P	P	P [3-6,8]
Peripheral Vascular	P	P	P		P	P	P	P [3-6,8,10]
Laparoscopic								
MSK Conventional	P	P	P		P	P	P	P [3-6,8]
MSK Superficial	P	P	P		P	P	P	P [3-6,8]
Vascular Access	P	P	P		P	P	P	P [3-6,8,10]
Nerve Block	P	P	P		P	P	P	P [3-6,8-9]
Other								

N = New indication; P = Previously cleared under K093462

Notes:

1. Abdominal organs and vascular
2. Breast, Thyroid, Testicle
3. Elastography
4. Panoramic Imaging
5. Compound Imaging
6. Freehand 3D Imaging
7. Live 3D/4D Imaging
8. Imaging for guidance of biopsy
9. Imaging for guidance of nerve block injections
10. Imaging for guidance of central or peripheral lines
11. Volume Navigation/Image Fusion/SonixGPS™ (available only with the GPS transducer)
12. B/M, B/PW Doppler or CW Doppler, B/C/PW Doppler (Triplex) or CW Doppler (Triplex CW), B/Power Doppler/PW Doppler or CW Doppler, Simultaneous Color Doppler or Power Doppler.

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DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

EC9-5/10 and EC9-5/10 GPS Microconvex Endocavity Radius Transducer

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

Clinical Application	Mode of Operation							
	B	M	PW Doppler	CW Doppler	Color Doppler	Power Doppler	Combined Modes[12]	Other [Notes]
Ophthalmic								
Fetal								
Abdominal								
Intraoperative[1]								
Intraoperative Neurological								
Pediatric								
Small Organ[2]								
Neonatal Cephalic								
Adult Cephalic								
Cardiac								
Transesophageal								
Transrectal	P	P	P		P	P	P	P [3-6,8,11]
Transvaginal	P	P	P		P	P	P	P [3-6,8,11]
Transurethral								
Transcranial								
Peripheral Vascular								
Laparoscopic								
MSK Conventional								
MSK Superficial								
Vascular Access								
Nerve Block								
Other								

N = New indication; P = Previously cleared under K093462

Notes:

1. Abdominal organs and vascular
2. Breast, Thyroid, Testicle
3. Elastography
4. Panoramic Imaging
5. Compound Imaging
6. Freehand 3D Imaging
7. Live 3D/4D Imaging
8. Imaging for guidance of biopsy
9. Imaging for guidance of nerve block injections
10. Imaging for guidance of central or peripheral lines
11. Volume Navigation/Image Fusion/SonixGPS™ (available only with the GPS transducer)
12. B/M, B/PW Doppler or CW Doppler, B/C/PW Doppler (Triplex) or CW Doppler (Triplex CW), B/Power Doppler/PW Doppler or CW Doppler, Simultaneous Color Doppler or Power Doppler.

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DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

HST15-8/20 Linear Transducer

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

Clinical Application	Mode of Operation							
	B	M	PW Doppler	CW Doppler	Color Doppler	Power Doppler	Combined Modes[12]	Other [Notes]
Ophthalmic								
Fetal								
Abdominal								
Intraoperative[1]								
Intraoperative Neurological	P	P	P		P	P	P	P [3-6,8]
Pediatric	P	P	P		P	P	P	P [3-6,8]
Small Organ[2]	P	P	P		P	P	P	P [3-6,8]
Neonatal Cephalic	P	P	P		P	P	P	P [3-6,8]
Adult Cephalic								
Cardiac								
Transesophageal								
Transrectal								
Transvaginal								
Transurethral								
Transcranial	P	P	P		P	P	P	P [3-6,8]
Peripheral Vascular	P	P	P		P	P	P	P [3-6,8]
Laparoscopic								
MSK Conventional	P	P	P		P	P	P	P [3-6,8]
MSK Superficial	P	P	P		P	P	P	P [3-6,8]
Vascular Access	P	P	P		P	P	P	P [3-6,8,10]
Nerve Block	P	P	P		P	P	P	P [3-6,8,9]
Other								

N = New indication; P = Previously cleared under K093462

Notes:

1. Abdominal organs and vascular
2. Breast, Thyroid, Testicle
3. Elastography
4. Panoramic Imaging
5. Compound Imaging
6. Freehand 3D Imaging
7. Live 3D/4D Imaging
8. Imaging for guidance of biopsy
9. Imaging for guidance of nerve block injections
10. Imaging for guidance of central or peripheral lines
11. Volume Navigation/Image Fusion/SonixGPS™ (available only with the GPS transducer)
12. B/M, B/PW Doppler or CW Doppler, B/C/PW Doppler (Triplex) or CW Doppler (Triplex CW), B/Power Doppler/PW Doppler or CW Doppler, Simultaneous Color Doppler or Power Doppler.

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DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

L9-4/38 Linear Transducers

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

Clinical Application	Mode of Operation							
	B	M	PW Doppler	CW Doppler	Color Doppler	Power Doppler	Combined Modes[12]	Other [Notes]
Ophthalmic								
Fetal	P	P	P		P	P	P	P [3-6,8]
Abdominal	P	P	P		P	P	P	P [3-6,8]
Intraoperative[1]								
Intraoperative Neurological								
Pediatric	P	P	P		P	P	P	P [3-6,8]
Small Organ[2]	P	P	P		P	P	P	P [3-6,8]
Neonatal Cephalic	P	P	P		P	P	P	P [3-6,8]
Adult Cephalic	P	P	P		P	P	P	P [3-6,8]
Cardiac								
Transesophageal								
Transrectal								
Transvaginal								
Transurethral								
Transcranial								
Peripheral Vascular	P	P	P		P	P	P	P [3-6,8]
Laparoscopic								
MSK Conventional	P	P	P		P	P	P	P [3-6,8]
MSK Superficial	P	P	P		P	P	P	P [3-6,8]
Vascular Access	P	P	P		P	P	P	P [3-6,8,10]
Nerve Block	P	P	P		P	P	P	P [3-6,8,9]
Other								

N = New indication; P = Previously cleared under K093462

Notes:

1. Abdominal organs and vascular
2. Breast, Thyroid, Testicle
3. Elastography
4. Panoramic Imaging
5. Compound Imaging
6. Freehand 3D Imaging
7. Live 3D/4D Imaging
8. Imaging for guidance of biopsy
9. Imaging for guidance of nerve block injections
10. Imaging for guidance of central or peripheral lines
11. Volume Navigation/Image Fusion/SonixGPS™ (available only with the GPS transducer)
12. B/M, B/PW Doppler or CW Doppler, B/C/PW Doppler (Triplex) or CW Doppler (Triplex CW), B/Power Doppler/PW Doppler or CW Doppler, Simultaneous Color Doppler or Power Doppler.

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DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

L14-5/38 and L14-5/38 GPS Linear Transducers

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

Clinical Application	Mode of Operation							
	B	M	PW Doppler	CW Doppler	Color Doppler	Power Doppler	Combined Modes[12]	Other [Notes]
Ophthalmic								
Fetal	P	P	P		P	P	P	P [3-6,8,11]
Abdominal	P	P	P		P	P	P	P [3-6,8,11]
Intraoperative[1]								
Intraoperative Neurological								
Pediatric	P	P	P		P	P	P	P [3-6,8,11]
Small Organ[2]	P	P	P		P	P	P	P [3-6,8,11]
Neonatal Cephalic	P	P	P		P	P	P	P [3-6,8,11]
Adult Cephalic	P	P	P		P	P	P	P [3-6,8,11]
Cardiac								
Transesophageal								
Transrectal								
Transvaginal								
Transurethral								
Transcranial								
Peripheral Vascular	P	P	P		P	P	P	P [3-6,8,11]
Laparoscopic								
MSK Conventional	P	P	P		P	P	P	P [3-6,8,11]
MSK Superficial	P	P	P		P	P	P	P [3-6,8,11]
Vascular Access	P	P	P		P	P	P	P [3-6,8,10,11]
Nerve Block	P	P	P		P	P	P	P [3-6,8,9,11]
Other								

N = New indication; P = Previously cleared under K093462

Notes:

1. Abdominal organs and vascular
2. Breast, Thyroid, Testicle
3. Elastography
4. Panoramic Imaging
5. Compound Imaging
6. Freehand 3D Imaging
7. Live 3D/4D Imaging
8. Imaging for guidance of biopsy
9. Imaging for guidance of nerve block injections
10. Imaging for guidance of central or peripheral lines
11. Volume Navigation/Image Fusion/SonixGPS™ (available only with the GPS transducer)
12. B/M, B/PW Doppler or CW Doppler, B/C/PW Doppler (Triplex) or CW Doppler (Triplex CW), B/Power Doppler/PW Doppler or CW Doppler, Simultaneous Color Doppler or Power Doppler.

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DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

L14-5W/60 Wide Linear Transducer

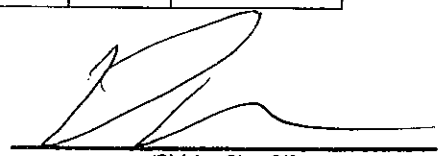
Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation							
	B	M	PW Doppler	CW Doppler	Color Doppler	Power Doppler	Combined Modes[12]	Other [Notes]
Ophthalmic								
Fetal	P	P	P		P	P	P	P [3-6,8]
Abdominal	P	P	P		P	P	P	P [3-6,8]
Intraoperative[1]								
Intraoperative Neurological								
Pediatric	P	P	P		P	P	P	P [3-6,8]
Small Organ[2]	P	P	P		P	P	P	P [3-6,8]
Neonatal Cephalic	P	P	P		P	P	P	P [3-6,8]
Adult Cephalic	P	P	P		P	P	P	P [3-6,8]
Cardiac								
Transesophageal								
Transrectal								
Transvaginal								
Transurethral								
Transcranial								
Peripheral Vascular	P	P	P		P	P	P	P [3-6,8]
Laparoscopic								
MSK Conventional	P	P	P		P	P	P	P [3-6,8]
MSK Superficial	P	P	P		P	P	P	P [3-6,8]
Vascular Access	P	P	P		P	P	P	P [3-6,8,10]
Nerve Block	P	P	P		P	P	P	P [3-6,8,9]
Other								

N = New indication; P = Previously cleared under K093462

Notes:

1. Abdominal organs and vascular
2. Breast, Thyroid, Testicle
3. Elastography
4. Panoramic Imaging
5. Compound Imaging
6. Freehand 3D Imaging
7. Live 3D/4D Imaging
8. Imaging for guidance of biopsy
9. Imaging for guidance of nerve block injections
10. Imaging for guidance of central or peripheral lines
11. Volume Navigation/Image Fusion/SonixGPS™ (available only with the GPS transducer)
12. B/M, B/PW Doppler or CW Doppler, B/C/PW Doppler (Triplex) or CW Doppler (Triplex CW), B/Power Doppler/PW Doppler or CW Doppler, Simultaneous Color Doppler or Power Doppler.



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DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

PA7-4/12 Phased Array Transducer

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

Clinical Application	Mode of Operation							
	B	M	PW Doppler	CW Doppler	Color Doppler	Power Doppler	Combined Modes[12]	Other [Notes]
Ophthalmic								
Fetal								
Abdominal	P	P	P	P	P	P	P	P [3-6,8]
Intraoperative[1]								
Intraoperative Neurological								
Pediatric	P	P	P	P	P	P	P	P [3-6,8]
Small Organ[2]								
Neonatal Cephalic	P	P	P		P	P	P	P [3-6,8]
Adult Cephalic	P	P	P	P	P	P	P	P [3-6,8]
Cardiac	P	P	P	P	P	P	P	P [3-6,8]
Transesophageal								
Transrectal								
Transvaginal								
Transurethral								
Transcranial	P	P	P	P	P	P	P	P [3-6,8]
Peripheral Vascular								
Laparoscopic								
MSK Conventional								
MSK Superficial								
Vascular Access								
Nerve Block								
Other								

N = New indication; P = Previously cleared under K093462

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510K K102997

Notes:

1. Abdominal organs and vascular
2. Breast, Thyroid, Testicle
3. Elastography
4. Panoramic Imaging
5. Compound Imaging
6. Freehand 3D Imaging
7. Live 3D/4D Imaging
8. Imaging for guidance of biopsy
9. Imaging for guidance of nerve block injections
10. Imaging for guidance of central or peripheral lines
11. Volume Navigation/Image Fusion/SonixGPS™ (available only with the GPS transducer)
12. B/M, B/PW Doppler or CW Doppler, B/C/PW Doppler (Triplex) or CW Doppler (Triplex CW), B/Power Doppler/PW Doppler or CW Doppler, Simultaneous Color Doppler or Power Doppler.

Prescription Use Only

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

SA4-2/24 Phased Array Transducer

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

Clinical Application	Mode of Operation							
	B	M	PW Doppler	CW Doppler	Color Doppler	Power Doppler	Combined Modes[12]	Other [Notes]
Ophthalmic								
Fetal								
Abdominal	P	P	P	P	P	P	P	P [3-6,8]
Intraoperative[1]								
Intraoperative Neurological								
Pediatric	P	P	P	P	P	P	P	P [3-6,8]
Small Organ[2]								
Neonatal Cephalic	P	P	P		P	P	P	P [3-6,8]
Adult Cephalic	P	P	P	P	P	P	P	P [3-6,8]
Cardiac	P	P	P	P	P	P	P	P [3-6,8]
Transesophageal								
Transrectal								
Transvaginal								
Transurethral								
Transcranial	P	P	P	P	P	P	P	P [3-6,8]
Peripheral Vascular								
Laparoscopic								
MSK Conventional								
MSK Superficial								
Vascular Access								
Nerve Block								
Other								

N = New indication; P = Previously cleared under K093462

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Notes:

1. Abdominal organs and vascular
2. Breast, Thyroid, Testicle
3. Elastography
4. Panoramic Imaging
5. Compound Imaging
6. Freehand 3D Imaging
7. Live 3D/4D Imaging
8. Imaging for guidance of biopsy
9. Imaging for guidance of nerve block injections
10. Imaging for guidance of central or peripheral lines
11. Volume Navigation/Image Fusion/SonixGPS™ (available only with the GPS transducer)
12. B/M, B/PW Doppler or CW Doppler, B/C/PW Doppler (Triplex) or CW Doppler (Triplex CW), B/Power Doppler/PW Doppler or CW Doppler, Simultaneous Color Doppler or Power Doppler.

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DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

mTEE8-3/5 Transesophageal Phased Array Radius Transducer

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

Clinical Application	Mode of Operation							
	B	M	PW Doppler	CW Doppler	Color Doppler	Power Doppler	Combined Modes[12]	Other [Notes]
Ophthalmic								
Fetal								
Abdominal								
Intraoperative[1]								
Intraoperative Neurological								
Pediatric								
Small Organ[2]								
Neonatal Cephalic								
Adult Cephalic								
Cardiac								
Transesophageal	P	P	P	P	P	P	P	
Transrectal								
Transvaginal								
Transurethral								
Transcranial								
Peripheral Vascular								
Laparoscopic								
MSK Conventional								
MSK Superficial								
Vascular Access								
Nerve Block								
Other								

N = New indication; P = Previously cleared under K093462

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Notes:

1. Abdominal organs and vascular
2. Breast, Thyroid, Testicle
3. Elastography
4. Panoramic Imaging
5. Compound Imaging
6. Freehand 3D Imaging
7. Live 3D/4D Imaging
8. Imaging for guidance of biopsy
9. Imaging for guidance of nerve block injections
10. Imaging for guidance of central or peripheral lines
11. Volume Navigation/Image Fusion/SonixGPS™ (available only with the GPS transducer)
12. B/M, B/PW Doppler or CW Doppler, B/C/PW Doppler (Triplex) or CW Doppler (Triplex CW), B/Power Doppler/PW Doppler or CW Doppler, Simultaneous Color Doppler or Power Doppler.

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