

K093462

510 (k) Summary for the Sonix Ultrasound Scanner

This summary of safety and effectiveness is provided as part of this Premarket Notification in compliance with the Safe Medical Devices Act of 1990 revisions to 21 CFR, Part 807.92, Content and format of a 510(k) summary.

1.0 Submitter Information

1.1 Submitter

Ultrasonix Medical Corporation
130-4311 Viking Way
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Canada V6V 2K9
(t) 604-279-8550
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NOV 20 2009

1.2 Contact

Chas Yu, Quality Assurance Manager
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1.3 Date Prepared

October 10, 2008

2.0 Device Name

2.1 Common Name

Ultrasound Imaging System

2.2 Proprietary Name

Sonix 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 TOUCH Ultrasound Scanner (K083095)
SONIX MDP Ultrasound Scanner (K080935)
GE Logiq E9 (K082185)
Ultraguide 1000 (K974432)
Aegis (K070244)
SonoSite MicroMaxx High Resolution Ultrasound System (K053069)
Philips HD 11 Diagnostic Ultrasound System (K062247)
GE Logiq P5 and A5 (K060993)
Imacor Zura TEE System (K080223)
Siemens S2000 Diagnostic Ultrasound System (K072786)
Volcano S5i Family of Ultrasound Systems (K061215)

2.6 Reason for submission:

Clearance request for:

Sonix Ultrasound Scanner and the cleared transducers with additional/expanded indication for use:

- Imaging of guidance of central or peripheral lines;
- Imaging for guidance of biopsy;
- Imaging for guidance of nerve block injections;
- Volume Navigation/ Image Fusion/ GPS
- Panoramic imaging;
- Compound imaging;
- Elastography.

New Transducers:

- SA4-2/24
- SA3-1/24
- 4DL14-5/38
- 4DEC9-5/10
- MC9-4/12
- HST15-8/20
- L15-8/26
- TEM7-3/9
- TEM10-7/5
- TEEIMA

Name change request

N/A

New product clearance for:

N/A

2.7 Device description

The Sonix 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 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 Sonix 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	2-15MHz
Transducer types	Linear array Curved array TEE array Intracavity array Phased array

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

EN 60601-1	European Norm, Medical Electrical Equipment
UL 2601-1	Underwriters Laboratories Standards, Medical Electrical Equipment
C22-2 No 601.1	Canadian Standards Association, Medical Electrical Equipment
EN 60601-1-2	European Norm, Collateral Standard, Electromagnetic Compatibility
IEC 60601-2-37	Particular requirements for the safety of ultrasonic medical diagnostic equipment
AIUM AOL	Acoustic Output Labeling Standard for Diagnostic Ultrasound Equipment
AIUM RTD	Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices

3.0 Summary of Intended Uses

The Sonix Ultrasound Imaging System is intended for the following applications: Ophthalmic, Abdominal, Cardiac, Intraoperative (specific), 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 Sonix 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 Sonix 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 TOUCH Ultrasound Scanner (K083095)
Sonix MDP Ultrasound Scanner (K080935)
Ultraguide 1000 (K974432)
GE Logiq E9 (K082185)
Aegis (K070244)

SonoSite MicroMaxx High Resolution Ultrasound System (K053069)
 Philips HD 11 Diagnostic Ultrasound System (K062247)
 GE Logiq P5 and A5 (K060993)
 Imacor Zura TEE System (K080223)
 Siemens S2000 Diagnostic Ultrasound System (K072786)
 Volcano S5i Family of Ultrasound Systems (K061215)

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 Sonix Ultrasound Scanner is designed to comply with the "Standard For Real Time Display Of Thermal And Mechanical Acoustic Output Indices On Diagnostic Ultrasound Equipment (1992)" published by the National Electrical Manufacturers Association as UD-3.

With respect to limits on acoustic outputs, the Sonix Ultrasound Scanner complies with the guideline limits set in the September 30, 1997 revision of 510(k) Diagnostic Ultrasound Guidance.

With regard to general safety, the Sonix Ultrasound Scanner is designed to comply with IEC 601-1 (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:

ISPTA (d)	720mW/cm ²
TIS/TIB/TIC	0.1 – 4.0 (Range)
Mechanical Index (MI)	1.9 (Maximum)
ISPPA (d)	0 – 700W/cm ² (Range)

The limits are the same as predicate Track 3 devices.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-066-0609
Silver Spring, MD 20993-0002

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

NOV 20 2009

Re: K093462
Trade/Device Name: Sonix 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: November 5, 2009
Received: November 6, 2009

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 Sonix Ultrasound Scanner Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

SA4-2/24 Phased Array

SA3-1/24 Phased Array

PA4-2/20 Phased Array

PA7-4 Phased Array

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

L9-4/38 Linear

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

C5-2/40 Convex

L15-8/26 Linear

BPSL9-5/55-10L Linear Endocavity Biplane

BPSL9-5/55-10C Microconvex Endocavity Biplane

HST15-8/20 Linear

4DC7-3/40 Motorized Convex

4DL14-5/38 Motorized Linear

L14-5W/60 Wide Linear

4DEC9-5/10 Motorized Microconvex Endocavity

T7-4 Transesophageal Phased Array

TEM7-3/9 Transesophageal

TEM10-7/5 Transesophageal

TEEIMA Transesophageal

IOT9-5/40 Convex Intraoperational

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 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); 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.

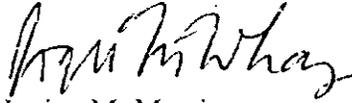
This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

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/CDRHOices/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.

Page 3 - Mr. Mark Job

If you have any questions regarding the content of this letter, please contact Mr. Paul Hardy at (301) 796-6542.

Sincerely yours,



fm Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

Indications for Use

510(k) Number (if known): K093462

Device Name: Sonix Ultrasound Scanner

Indications For Use:

The Sonix Ultrasound Scanner is intended for the following applications:
Ophthalmic, Abdominal, Cardiac, Intraoperative (specific), 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
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(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)

Page 1 of 1

Robert M. Why
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices

510(k) Number K093462

ULTRASOUND INDICATIONS FOR USE TABLES

Sonix Ultrasound Scanner – Diagnostic Ultrasound Indications for Use Form

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	N	N	N		N	N	N	N[3-6,8]
Fetal	P	P	P	N	P	P	P	P[6-8] N[3-5,11]
Abdominal	P	P	P	P	P	P	P	P[6-8] N[3-5,11]
Intraoperative ¹	P	P	P		P	P	P	P[6,7] N[3-5,8]
Intraoperative Neurological	P	P	P		P	P	P	P[6,7] N[3-5,8]
Pediatric	P	P	P	P	P	P	P	P[6-8] N[3-5,11]
Small Organ ²	P	P	P	N	P	P	P	P[6-8] N[3-5,11]
Neonatal Cephalic	P	P	P	N	P	P	P	P[3-6,8] N[11]
Adult Cephalic	P	P	P	N	P	P	P	P[3-6,8] N[11]
Cardiac	P	P	P	P	P	P	P	P[3-6,8]
Transesophageal	P	P	P	N	P	P	P	P[3-6,8]
Transrectal	P	P	P	N	P	P	P	P[6-8] N[3-5,11]
Transvaginal	P	P	P	N	P	P	P	P[6-8] N[3-5,11]
Transurethral								
Transcranial	P	P	P	N	P	P	P	P[3-6,8]
Peripheral Vascular	P	P	P	N	P	P	P	P[6-8] N[3-5,11]
Laparoscopic								
MSK Conventional	P	P	P	N	P	P	P	P[6-8] N[3-5,11]
MSK Superficial	P	P	P	N	P	P	P	P[6-8] N[3-5,11]
Vascular Access	N	N	N	N	N	N	N	N[3-8,10,11]
Nerve Block	N	N	N	N	N	N	N	N[3-9,11]
Other								

N = New indication; P = Previously cleared under K061827

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 / GPS (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



 (Division Sign-Off)
 Division of Reproductive, Abdominal,
 and Radiological Devices
 §10(k) Number K093462

ULTRASOUND INDICATIONS FOR USE TABLES

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	N	N	N	N	N	N	N	N[3-6,8]
Intraoperative ¹								
Intraoperative Neurological								
Pediatric	N	N	N	N	N	N	N	N[3-6,8]
Small Organ ²								
Neonatal Cephalic	N	N	N		N	N	N	N[3-6,8]
Adult Cephalic	N	N	N	N	N	N	N	N[3-6,8]
Cardiac	N	N	N	N	N	N	N	N[3-6,8]
Transesophageal								
Transrectal								
Transvaginal								
Transurethral								
Transcranial	N	N	N	N	N	N	N	N[3-6,8]
Peripheral Vascular								
Laparoscopic								
MSK Conventional								
MSK Superficial								
Vascular Access								
Nerve Block								
Other								

N = New indication; P = Previously cleared

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 / GPS (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



 (Division Sign-Off)
 Division of Reproductive, Abdominal,
 and Radiological Devices
 510(k) Number K093462

ULTRASOUND INDICATIONS FOR USE TABLES

SA3-1/24 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	N	N	N	N	N	N	N	N[3-6,8]
Intraoperative ¹								
Intraoperative Neurological								
Pediatric	N	N	N	N	N	N	N	N[3-6,8]
Small Organ ²								
Neonatal Cephalic	N	N	N		N	N	N	N[3-6,8]
Adult Cephalic	N	N	N	N	N	N	N	N[3-6,8]
Cardiac	N	N	N	N	N	N	N	N[3-6,8]
Transesophageal								
Transrectal								
Transvaginal								
Transurethral								
Transcranial	N	N	N	N	N	N	N	N[3-6,8]
Peripheral Vascular								
Laparoscopic								
MSK Conventional								
MSK Superficial								
Vascular Access								
Nerve Block								
Other								

N = New indication; P = Previously cleared

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 / GPS (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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 Division of Reproductive, Abdominal,
 and Radiological Devices
 510(k) Number K093462

ULTRASOUND INDICATIONS FOR USE TABLES

PA4-2/20 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[6] N[3-5,8]
Intraoperative ¹								
Intraoperative Neurological								
Pediatric	P	P	P	P	P	P	P	P[6] N[3-5,8]
Small Organ ²								
Neonatal Cephalic	P	P	P		P	P	P	P[6] N[3-5,8]
Adult Cephalic	P	P	P	N	P	P	P	P[6] N[3-5,8]
Cardiac	P	P	P	P	P	P	P	P[6] N[3-5,8]
Transesophageal								
Transrectal								
Transvaginal								
Transurethral								
Transcranial	P	P	P	N	P	P	P	P[6] N[3-5,8]
Peripheral Vascular								
Laparoscopic								
MSK Conventional								
MSK Superficial								
Vascular Access								
Nerve Block								
Other								

N = New indication; P = Previously cleared under K061827

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 / GPS (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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 Division of Reproductive, Abdominal,
 and Radiological Devices

510(k) Number 2093462

ULTRASOUND INDICATIONS FOR USE TABLES

PA7-4 Phased Array Transducer

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

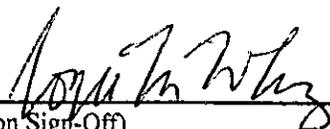
Clinical Application	Mode of Operation							
	B	M	PW Doppler	CW Doppler	Color Doppler	Power Doppler	Combined Modes ¹²	Other [Notes]
Ophthalmic								
Fetal								
Abdominal	P	P	P	P	P	P	P	P[6] N[3-5,8]
Intraoperative ¹								
Intraoperative Neurological								
Pediatric	P	P	P	P	P	P	P	P[6] N[3-5,8]
Small Organ ²								
Neonatal Cephalic	P	P	P		P	P	P	P[6] N[3-5,8]
Adult Cephalic	P	P	P	N	P	P	P	P[6] N[3-5,8]
Cardiac	P	P	P	P	P	P	P	P[6] N[3-5,8]
Transesophageal								
Transrectal								
Transvaginal								
Transurethral								
Transcranial	P	P	P	N	P	P	P	P[6] N[3-5,8]
Peripheral Vascular								
Laparoscopic								
MSK Conventional								
MSK Superficial								
Vascular Access								
Nerve Block								
Other								

N = New indication; P = Previously cleared under K061827

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 / GPS (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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 Division of Reproductive, Abdominal,
 and Radiological Devices

510(k) Number

R093462

ULTRASOUND INDICATIONS FOR USE TABLES

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:

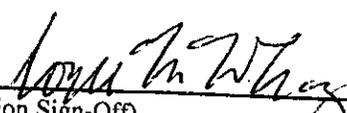
Clinical Application	Mode of Operation							
	B	M	PW Doppler	CW Doppler	Color Doppler	Power Doppler	Combined Modes ¹²	Other [Notes]
Ophthalmic								
Fetal	P	P	P		P	P	P	P[6,8] N[3-5,11]
Abdominal	P	P	P		P	P	P	P[6,8] N[3-5,11]
Intraoperative ¹								
Intraoperative Neurological								
Pediatric	P	P	P		P	P	P	P[6,8] N[3-5,11]
Small Organ ²	P	P	P		P	P	P	P[6,8] N[3-5,11]
Neonatal Cephalic								
Adult Cephalic								
Cardiac								
Transesophageal								
Transrectal								
Transvaginal								
Transurethral								
Transcranial								
Peripheral Vascular	P	P	P		P	P	P	P[6,8] N[3-5,11]
Laparoscopic								
MSK Conventional	P	P	P		P	P	P	P[6,8] N[3-5,11]
MSK Superficial	P	P	P		P	P	P	P[6,8] N[3-5,11]
Vascular Access								
Nerve Block								
Other								

N = New indication; P = Previously cleared under K061827

Notes:

- 1 Abdominal organs and vascular
- 2 Breast, Thyroid, Testicle
- 3 Elastography
- 4 Panoramic Imaging
- 5 Compound Imaging
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- 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 / GPS (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


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 and Radiological Devices
 S10(k) Number K093462

ULTRASOUND INDICATIONS FOR USE TABLES

C5-2/40 Convex Transducer

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

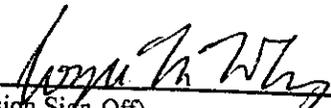
Clinical Application	Mode of Operation							
	B	M	PW Doppler	CW Doppler	Color Doppler	Power Doppler	Combined Modes ¹²	Other (Notes)
Ophthalmic								
Fetal	P	P	P		P	P	P	P[6] N[3-5,8]
Abdominal	P	P	P		P	P	P	P[6] N[3-5,8]
Intraoperative ¹								
Intraoperative Neurological								
Pediatric	P	P	P		P	P	P	P[6] N[3-5,8]
Small Organ ²	P	P	P		P	P	P	P[6] N[3-5,8]
Neonatal Cephalic								
Adult Cephalic								
Cardiac								
Transesophageal								
Transrectal								
Transvaginal								
Transurethral								
Transcranial								
Peripheral Vascular	P	P	P		P	P	P	P[6] N[3-5,8]
Laparoscopic								
MSK Conventional	P	P	P		P	P	P	P[6] N[3-5,8]
MSK Superficial	P	P	P		P	P	P	P[6] N[3-5,8]
Vascular Access								
Nerve Block								
Other								

N = New indication; P = Previously cleared under K061827

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 / GPS (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



 (Division Sign-Off)
 Division of Reproductive, Abdominal,
 and Radiological Devices
 510(k) Number K093462

ULTRASOUND INDICATIONS FOR USE TABLES

C7-3/50 Convex Transducer

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

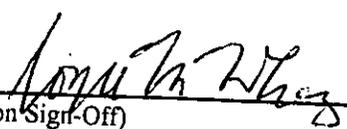
Clinical Application	Mode of Operation							
	B	M	PW Doppler	CW Doppler	Color Doppler	Power Doppler	Combined Modes ¹²	Other (Notes)
Ophthalmic								
Fetal	P	P	P		P	P	P	P[6,8] N[3-5]
Abdominal	P	P	P		P	P	P	P[6,8] N[3-5]
Intraoperative ¹								
Intraoperative Neurological								
Pediatric	P	P	P		P	P	P	P[6,8] N[3-5]
Small Organ ²	P	P	P		P	P	P	P[6,8] N[3-5]
Neonatal Cephalic	P	P	P		P	P	P	P[6,8] N[3-5]
Adult Cephalic	P	P	P		P	P	P	P[6,8] N[3-5]
Cardiac								
Transesophageal								
Transrectal								
Transvaginal								
Transurethral								
Transcranial								
Peripheral Vascular	P	P	P		P	P	P	P[6,8] N[3-5]
Laparoscopic								
MSK Conventional	P	P	P		P	P	P	P[6,8] N[3-5]
MSK Superficial	P	P	P		P	P	P	P[6,8] N[3-5]
Vascular Access								
Nerve Block								
Other								

N = New indication; P = Previously cleared under K061827

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 / GPS (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



 (Division Sign-Off)
 Division of Reproductive, Abdominal,
 and Radiological Devices
 510(k) Number K093462

ULTRASOUND INDICATIONS FOR USE TABLES

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	N	N	N	N	N	N	N	N[3-6,8]
Abdominal	N	N	N	N	N	N	N	N[3-6,8]
Intraoperative ¹								
Intraoperative Neurological								
Pediatric	N	N	N	N	N	N	N	N[3-6,8]
Small Organ ²	N	N	N	N	N	N	N	N[3-6,8]
Neonatal Cephalic	N	N	N	N	N	N	N	N[3-6,8]
Adult Cephalic	N	N	N	N	N	N	N	N[3-6,8]
Cardiac								
Transesophageal								
Transrectal								
Transvaginal								
Transurethral								
Transcranial	N	N	N	N	N	N	N	N[3-6,8]
Peripheral Vascular	N	N	N	N	N	N	N	N[3-6,8]
Laparoscopic								
MSK Conventional	N	N	N	N	N	N	N	N[3-6,8]
MSK Superficial	N	N	N	N	N	N	N	N[3-6,8]
Vascular Access	N	N	N	N	N	N	N	N[3-6,8,10]
Nerve Block	N	N	N	N	N	N	N	N[3-6,8,9]
Other								

N = New indication; P = Previously cleared

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 / GPS (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


 (Division Sign-Off)
 Division of Reproductive, Abdominal,
 and Radiological Devices
 510(k) Number: K093462

ULTRASOUND INDICATIONS FOR USE TABLES

EC9-5/10 and EC9-5/10 GPS Microconvex Endocavity 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								
Abdominal								
Intraoperative ¹								
Intraoperative Neurological								
Pediatric								
Small Organ ²								
Neonatal Cephalic								
Adult Cephalic								
Cardiac								
Transesophageal								
Transrectal	P	P	P		P	P	P	P[6.8] N[3-5,11]
Transvaginal	P	P	P		P	P	P	P[6.8] N[3-5,11]
Transurethral								
Transcranial								
Peripheral Vascular								
Laparoscopic								
MSK Conventional								
MSK Superficial								
Vascular Access								
Nerve Block								
Other								

N = New indication; P = Previously cleared under K061827

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 / GPS (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


 (Division Sign-Off)
 Division of Reproductive, Abdominal,
 and Radiological Devices
 510(k) Number K093462

ULTRASOUND INDICATIONS FOR USE TABLES

L9-4/38 Linear Transducer

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

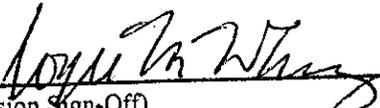
Clinical Application	Mode of Operation							
	B	M	PW Doppler	CW Doppler	Color Doppler	Power Doppler	Combined Modes ¹²	Other [Notes]
Ophthalmic								
Fetal	P	P	P		P	P	P	P[6,8] N[3-5]
Abdominal	P	P	P		P	P	P	P[6,8] N[3-5]
Intraoperative ¹								
Intraoperative Neurological								
Pediatric	P	P	P		P	P	P	P[6,8] N[3-5]
Small Organ ²	P	P	P		P	P	P	P[6,8] N[3-5]
Neonatal Cephalic	P	P	P		P	P	P	P[6,8] N[3-5]
Adult Cephalic	P	P	P		P	P	P	P[6,8] N[3-5]
Cardiac								
Transesophageal								
Transrectal								
Transvaginal								
Transurethral								
Transcranial								
Peripheral Vascular	P	P	P		P	P	P	P[6,8] N[3-5]
Laparoscopic								
MSK Conventional	P	P	P		P	P	P	P[6,8] N[3-5]
MSK Superficial	P	P	P		P	P	P	P[6,8] N[3-5]
Vascular Access	N	N	N		N	N	N	N[3-6,8,10]
Nerve Block	N	N	N		N	N	N	N[3-6,8,9]
Other								

N = New indication; P = Previously cleared under K061827

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 / GPS (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


 (Division Sign-Off)
 Division of Reproductive, Abdominal,
 and Radiological Devices
 510(k) Number K093462

ULTRASOUND INDICATIONS FOR USE TABLES

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:

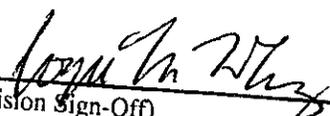
Clinical Application	Mode of Operation							
	B	M	PW Doppler	CW Doppler	Color Doppler	Power Doppler	Combined Modes ¹²	Other (Notes)
Ophthalmic								
Fetal	P	P	P		P	P	P	P[6,8] N[3-5,11]
Abdominal	P	P	P		P	P	P	P[6,8] N[3-5,11]
Intraoperative ¹								
Intraoperative Neurological								
Pediatric	P	P	P		P	P	P	P[6,8] N[3-5,11]
Small Organ ²	P	P	P		P	P	P	P[6,8] N[3-5,11]
Neonatal Cephalic	P	P	P		P	P	P	P[6,8] N[3-5,11]
Adult Cephalic	P	P	P		P	P	P	P[6,8] N[3-5,11]
Cardiac								
Transesophageal								
Transrectal								
Transvaginal								
Transurethral								
Transcranial								
Peripheral Vascular	P	P	P		P	P	P	P[6,8] N[3-5,11]
Laparoscopic								
MSK Conventional	P	P	P		P	P	P	P[6,8] N[3-5,11]
MSK Superficial	P	P	P		P	P	P	P[6,8] N[3-5,11]
Vascular Access	N	N	N		N	N	N	N[3-6,8,10,11]
Nerve Block	N	N	N		N	N	N	N[3-6,8,9,11]
Other								

N = New Indication; P = Previously cleared under K061827

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 / GPS (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


 (Division Sign-Off)
 Division of Reproductive, Abdominal,
 and Radiological Devices
 510(k) Number K093462

ULTRASOUND INDICATIONS FOR USE TABLES

L14-5W/60 Wide Linear Transducer

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

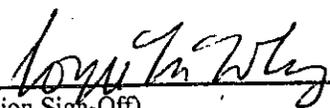
Clinical Application	Mode of Operation							
	B	M	PW Doppler	CW Doppler	Color Doppler	Power Doppler	Combined Modes ¹²	Other [Notes]
Ophthalmic								
Fetal	P	P	P		P	P	P	P[6,8] N[3-5]
Abdominal	P	P	P		P	P	P	P[6,8] N[3-5]
Intraoperative ¹								
Intraoperative Neurological								
Pediatric	P	P	P		P	P	P	P[6,8] N[3-5]
Small Organ ²	P	P	P		P	P	P	P[6,8] N[3-5]
Neonatal Cephalic	P	P	P		P	P	P	P[6,8] N[3-5]
Adult Cephalic	P	P	P		P	P	P	P[6,8] N[3-5]
Cardiac								
Transesophageal								
Transrectal								
Transvaginal								
Transurethral								
Transcranial								
Peripheral Vascular	P	P	P		P	P	P	P[6,8] N[3-5]
Laparoscopic								
MSK Conventional	P	P	P		P	P	P	P[6,8] N[3-5]
MSK Superficial	P	P	P		P	P	P	P[6,8] N[3-5]
Vascular Access	N	N	N		N	N	N	N[3-6,8,10]
Nerve Block	N	N	N		N	N	N	N[3-6,8,9]
Other								

N = New indication; **P** = Previously cleared under K061827

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 / GPS (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



 (Division Sign-Off)
 Division of Reproductive, Abdominal,
 and Radiological Devices
 510(k) Number K093462

ULTRASOUND INDICATIONS FOR USE TABLES

L15-8/26 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	N	N	N		N	N	N	N[3-6,8]
Fetal	N	N	N		N	N	N	N[3-6,8]
Abdominal								
Intraoperative ¹								
Intraoperative Neurological	N	N	N		N	N	N	N[3-6,8]
Pediatric	N	N	N		N	N	N	N[3-6,8]
Small Organ ²	N	N	N		N	N	N	N[3-6,8]
Neonatal Cephalic	N	N	N		N	N	N	N[3-6,8]
Adult Cephalic								
Cardiac								
Transesophageal								
Transrectal								
Transvaginal								
Transurethral								
Transcranial	N	N	N		N	N	N	N[3-6,8]
Peripheral Vascular	N	N	N		N	N	N	N[3-6,8]
Laparoscopic								
MSK Conventional	N	N	N		N	N	N	N[3-6,8]
MSK Superficial	N	N	N		N	N	N	N[3-6,8]
Vascular Access	N	N	N		N	N	N	N[3-6,8,10]
Nerve Block	N	N	N		N	N	N	N[3-6,8,9]
Other								

N = New indication; P = Previously cleared

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 / GPS (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


 (Division Sign-Off)
 Division of Reproductive, Abdominal,
 and Radiological Devices
 510(k) Number K093462

ULTRASOUND INDICATIONS FOR USE TABLES

BPSL9-5/55-10L Linear Endocavity Biplane Transducer

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

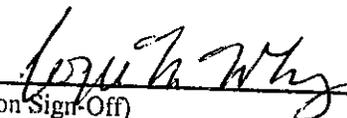
Clinical Application	Mode of Operation							
	B	M	PW Doppler	CW Doppler	Color Doppler	Power Doppler	Combined Modes ¹²	Other [Notes]
Ophthalmic								
Fetal								
Abdominal								
Intraoperative ¹								
Intraoperative Neurological								
Pediatric								
Small Organ ²								
Neonatal Cephalic								
Adult Cephalic								
Cardiac								
Transesophageal								
Transrectal	P	P	P	N	P	P	P	P[6] N[3-5,8]
Transvaginal	P	P	P	N	P	P	P	P[6] N[3-5,8]
Transurethral								
Transcranial								
Peripheral Vascular								
Laparoscopic								
MSK Conventional								
MSK Superficial								
Vascular Access								
Nerve Block								
Other								

N = New indication; P = Previously cleared under K061827

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 / GPS (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


 (Division Sign-Off)
 Division of Reproductive, Abdominal,
 and Radiological Devices
 510(k) Number K093462

ULTRASOUND INDICATIONS FOR USE TABLES

BPSL9-5/55-10C Microconvex Endocavity Biplane Transducer

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

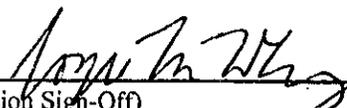
Clinical Application	Mode of Operation							
	B	M	PW Doppler	CW Doppler	Color Doppler	Power Doppler	Combined Modes ^{1,2}	Other [Notes]
Ophthalmic								
Fetal								
Abdominal								
Intraoperative ¹								
Intraoperative Neurological								
Pediatric								
Small Organ ²								
Neonatal Cephalic								
Adult Cephalic								
Cardiac								
Transesophageal								
Transrectal	P	P	P	N	P	P	P	P[6] N[3-5,8]
Transvaginal	P	P	P	N	P	P	P	P[6] N[3-5,8]
Transurethral								
Transcranial								
Peripheral Vascular								
Laparoscopic								
MSK Conventional								
MSK Superficial								
Vascular Access								
Nerve Block								
Other								

N = New indication; P = Previously cleared under K061827

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 / GPS (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


 (Division Sign-Off)
 Division of Reproductive, Abdominal,
 and Radiological Devices
 510(k) Number K093462

ULTRASOUND INDICATIONS FOR USE TABLES

HST15-8/20 Linear Transducer

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

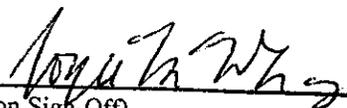
Clinical Application	Mode of Operation							
	B	M	PW Doppler	CW Doppler	Color Doppler	Power Doppler	Combined Modes ¹²	Other (Notes)
Ophthalmic	N	N	N		N	N	N	N[3-6,8]
Fetal	N	N	N		N	N	N	N[3-6,8]
Abdominal								
Intraoperative ¹								
Intraoperative Neurological	N	N	N		N	N	N	N[3-6,8]
Pediatric	N	N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

N = New indication; P = Previously cleared

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 / GPS (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


 (Division Sign-Off)
 Division of Reproductive, Abdominal,
 and Radiological Devices
 510(k) Number K093462

ULTRASOUND INDICATIONS FOR USE TABLES

4DC7-3/40 Motorized Convex Transducer

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

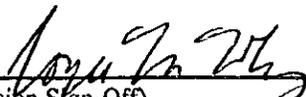
Clinical Application	Mode of Operation							
	B	M	PW Doppler	CW Doppler	Color Doppler	Power Doppler	Combined Modes ¹²	Other [Notes]
Ophthalmic								
Fetal	P	P	P		P	P	P	P[6,7] N[3-5,8]
Abdominal	P	P	P		P	P	P	P[6,7] N[3-5,8]
Intraoperative ¹								
Intraoperative Neurological								
Pediatric	P	P	P		P	P	P	P[6,7] N[3-5,8]
Small Organ ²	P	P	P		P	P	P	P[6,7] N[3-5,8]
Neonatal Cephalic								
Adult Cephalic								
Cardiac								
Transesophageal								
Transrectal								
Transvaginal								
Transurethral								
Transcranial								
Peripheral Vascular	P	P	P		P	P	P	P[6,7] N[3-5,8]
Laparoscopic								
MSK Conventional	P	P	P		P	P	P	P[6,7] N[3-5,8]
MSK Superficial	P	P	P		P	P	P	P[6,7] N[3-5,8]
Vascular Access								
Nerve Block								
Other								

N = New indication; P = Previously cleared K061827

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 / GPS (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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Division of Reproductive, Abdominal,
and Radiological Devices

510(k) Number

R093462

ULTRASOUND INDICATIONS FOR USE TABLES

4DL14-5/38 Motorized Linear Transducer

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

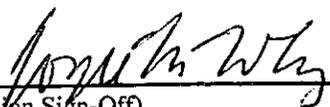
Clinical Application	Mode of Operation							
	B	M	PW Doppler	CW Doppler	Color Doppler	Power Doppler	Combined Modes ¹²	Other (Notes)
Ophthalmic								
Fetal	N	N	N		N	N	N	N[3-8]
Abdominal	N	N	N		N	N	N	N[3-8]
Intraoperative ¹								
Intraoperative Neurological								
Pediatric	N	N	N		N	N	N	N[3-8]
Small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

N = New indication; P = Previously cleared

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 / GPS (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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 Division of Reproductive, Abdominal,
 and Radiological Devices
 510(k) Number K093462

ULTRASOUND INDICATIONS FOR USE TABLES

4DEC9-5/10 Motorized Microconvex Endocavity 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	N	N	N	N	N	N	N	N[3-8]
Transvaginal	N	N	N	N	N	N	N	N[3-8]
Transurethral								
Transcranial								
Peripheral Vascular								
Laparoscopic								
MSK Conventional								
MSK Superficial								
Vascular Access								
Nerve Block								
Other								

N = New indication; P = Previously cleared

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 / GPS (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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 Division of Reproductive, Abdominal,
 and Radiological Devices
 510(k) Number K093462

ULTRASOUND INDICATIONS FOR USE TABLES

T7-4 Transesophageal Phased Array Transducer

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

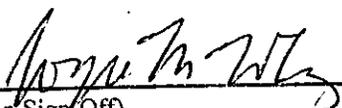
Clinical Application	Mode of Operation							
	B	M	PW Doppler	CW Doppler	Color Doppler	Power Doppler	Combined Modes ^{1,2}	Other (Notes)
Ophthalmic								
Fetal								
Abdominal								
Intraoperative ¹								
Intraoperative Neurological								
Pediatric								
Small Organ ²								
Neonatal Cephalic								
Adult Cephalic								
Cardiac								
Transesophageal	P	P	P	N	P	P	P	P[6] N[3-5,8]
Transrectal								
Transvaginal								
Transurethral								
Transcranial								
Peripheral Vascular								
Laparoscopic								
MSK Conventional								
MSK Superficial								
Vascular Access								
Nerve Block								
Other								

N = New indication; P = Previously cleared K061827

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 / GPS (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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 (Division Sign-Off)
 Division of Reproductive, Abdominal,
 and Radiological Devices
 510(k) Number K093462

ULTRASOUND INDICATIONS FOR USE TABLES

TEM7-3/9 Transesophageal 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	N	N	N	N	N	N	N	N[3-6,8]
Transrectal								
Transvaginal								
Transurethral								
Transcranial								
Peripheral Vascular								
Laparoscopic								
MSK Conventional								
MSK Superficial								
Vascular Access								
Nerve Block								
Other								

N = New indication; P = Previously cleared

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 / GPS (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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 Division of Reproductive, Abdominal,
 and Radiological Devices
 510(k) Number K093462

ULTRASOUND INDICATIONS FOR USE TABLES

TEM10-7/5 Transesophageal 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	N	N	N	N	N	N	N	N[3-6,8]
Transrectal								
Transvaginal								
Transurethral								
Transcranial								
Peripheral Vascular								
Laparoscopic								
MSK Conventional								
MSK Superficial								
Vascular Access								
Nerve Block								
Other								

N = New indication; P = Previously cleared

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 / GPS (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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 (Division Sign-Off)
 Division of Reproductive, Abdominal,
 and Radiological Devices
 510(k) Number K093462

ULTRASOUND INDICATIONS FOR USE TABLES

TEE/IMA Transesophageal Transducer

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

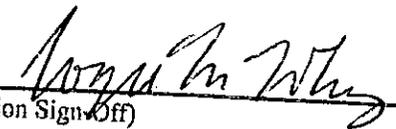
Clinical Application	Mode of Operation							
	B	M	PW Doppler	CW Doppler	Color Doppler	Power Doppler	Combined Modes ¹²	Other [Notes]
Ophthalmic								
Fetal								
Abdominal								
Intraoperative ¹								
Intraoperative Neurological								
Pediatric								
Small Organ ²								
Neonatal Cephalic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

N = New indication; P = Previously cleared

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 / GPS (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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 Division of Reproductive, Abdominal,
 and Radiological Devices
 510(k) Number K093462

ULTRASOUND INDICATIONS FOR USE TABLES

IOT9-5/40 Convex Intraoperational Transducer

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

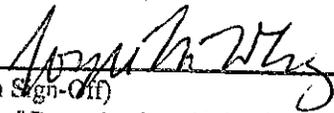
Clinical Application	Mode of Operation							
	B	M	PW Doppler	CW Doppler	Color Doppler	Power Doppler	Combined Modes ¹²	Other [Notes]
Ophthalmic								
Fetal	P	P	P		P	P	P	P[6,7] N[3-5,8]
Abdominal	P	P	P		P	P	P	P[6,7] N[3-5,8]
Intraoperative ¹	P	P	P		P	P	P	P[6,7] N[3-5,8]
Intraoperative Neurological	P	P	P		P	P	P	P[6,7] N[3-5,8]
Pediatric	P	P	P		P	P	P	P[6,7] N[3-5,8]
Small Organ ²	P	P	P		P	P	P	P[6,7] N[3-5,8]
Neonatal Cephalic								
Adult Cephalic								
Cardiac								
Transesophageal								
Transrectal	P	P	P		P	P	P	P[6,7] N[3-5,8]
Transvaginal	P	P	P		P	P	P	P[6,7] N[3-5,8]
Transurethral								
Transcranial								
Peripheral Vascular	P	P	P		P	P	P	P[6,7] N[3-5,8]
Laparoscopic								
MSK Conventional	P	P	P		P	P	P	P[6,7] N[3-5,8]
MSK Superficial	P	P	P		P	P	P	P[6,7] N[3-5,8]
Vascular Access								
Nerve Block								
Other								

N = New indication; P = Previously cleared under K061827

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 / GPS (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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K093462