SEP 16 2004 K042326

510 (k) Summary for the Ultrasonix Ergosonix 500 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
310-3480 Gilmore Way
Burnaby, British Columbia
Canada V5G 4Y1
(t) 604-437-9500
(f) 604-437-9502

1.2 Contact

Iulia Nuca, Quality Assurance
(t) 604-437-9500 x 112
(f) 604-437-9502
(e) **iulia@ultrasonix.com**

1.3 Date Prepared

August, 2004

2.0 Device Name

2.1 Common Name

Ultrasound Imaging System

2.2 Proprietary Name

Ergosonix Ultrasound Scanner
Modulo 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 IIa

2.5 Predicate Device:

Ultrasonix Ergosonix 500 Ultrasound Scanner (K020630)
ATL HDI 5000 System (K002003)
Acuson Sequoia (K973767)

2.6 Reason for submission:

Clearance request for new transducers, new applications and a new mode

Transducers:	PA4-2 PA3-2 PA7-4 L9-4 L12-5 L12-5W C5-1 60 C5-1 40 ER7 EC9-5 MC7 C7-4 L15-8 T7-4 3DEC9-5 3DC5-1 CC5-1 IOT7-4 IOJ7-4
Applications:	cardiac interventional intraoperative transcranial transesophageal
Imaging mode:	CW Doppler

Name change request

"Ultrasonix Ergosonix 500 Ultrasound Scanner", changed to "Ergosonix Ultrasound Scanner"

New product clearance

"MODULO Ultrasound Scanner"

2.7 Device description

The Ergosonix Ultrasound Scanner is a highly mobile, software-controlled, diagnostic ultrasound system capable of the following operating modes: 2D B-mode, M, Pulsed and CW Doppler, Color Flow (including amplitude Doppler). The system can generate real-time compound images and harmonic images.

The Modulo Ultrasound Scanner is identical to the Ergosonix Ultrasound Scanner, except that it has a different, smaller, enclosure. The Modulo Ultrasound Scanner has the same software and hardware as the Ergosonix Ultrasound Scanner, except for logo displays.

These systems have an electrocardiography (ECG) display feature and support 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 PA 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.

Frequency Range	2-15MHz
Transducer types	Linear array Curved array Intracavity array Phased array

The Egosonix and Modulo Ultrasound Scanners are designed to comply with the following standards:

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
EM 60601-1-1-2	European Norm, Collateral Standard, Electromagnetic Compatibility
IEC 60601-2-37	Particular requirements for the safety of ultrasonic medical diagnostic equipment
AIUM	Acoustic Output Labeling Standard for Diagnostic Ultrasound Equipment – Jan 1998
AIUM	Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices

3.0 Summary of Intended Uses

The Ergosonix and Modulo Ultrasound Scanners are intended for use in obstetrics/gynecology, general radiology, cardiac examinations by a qualified physician, to aid in the diagnosis and evaluation of soft tissues, by generating 2 dimensional images, time motion images and biometric studies. The specific intended uses of this system include: abdominal, small parts, peripheral vascular, musculo-skeletal (conventional), musculo-skeletal (superficial), cephalic, small organ (breast, thyroid, testicle), trans-vaginal, trans-rectal, pediatric and fetal imaging, cardiac (adult) and cardiac (pediatric), transcranial, transesophageal.

4.0 Comparison to Predicate Device

The Ergosonix and Modulo Ultrasound Scanners are substantially equivalent to the predicate devices with respect to intended use/indications for use, principles of operation and technological characteristics.

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 sounds 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) 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 sliders, depth control, base control and angling, among others.

6.0 Safety considerations

As track 3 ultrasound devices, the Ergosonix and Modulo Ultrasound Scanners are 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 Ergosonix and Modulo Ultrasound Scanners comply with the guideline limits set in the September 30, 1997 revision of 510(k) Diagnostic Ultrasound Guidance.

With regard to general safety, the Ergosonix and Modulo Ultrasound Scanners are 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:

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
9200 Corporate Boulevard
Rockville MD 20850

SEP 16 2004

Ms. Iulia Nuca
Quality Assurance
Ultrasonix Medical Corp.
310-3480 Gilmore Way
Burnaby, BC, V5G 4YI
CANADA

Re: K042326
Trade Name: Ergosonix / Modulo Ultrasound Scanners
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic trasducer
Regulatory Class: II
Product Code: 90 IYN, IYO, and ITX
Dated: August 25, 2004
Received: August 27, 2004

Dear Ms. Nuca:

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 Ergosonix / Modulo Ultrasound Scanners, as described in your premarket notification:

Transducer Model Number

C5-1 40 convex 1/5MHz 40mm radius transducer
C5-1 60 convex 1/5MHz 60mm radius transducer

L12-5 linear 5/12MHz 38mm transducer
L12-5W linear 5/12MHz 50mm transducer
L9-4 linear 4/9MHz 38mm transducer
PA3-2 phased array 2/3MHz transducer
PA4-2 phased array 2/4MHz transducer
PA3-2 phased array 2/4MHz transducer
PA7-4 phased array 4/7MHz transducer
ER7 biplane endocavity 5/9MHz transducer
EC9-5microconvex endocavity 5/9MHz 10mm radius transducer
MC7 microconvex 5/9MHz 10mm radius transducer
L15-8 linear 8/15MHz 29mm transducer
C7-4 convex 4/7MHz 40mm radius transducer
CC5-1 microconvex 1/5MHz 15mm radius transducer
T7-4 TEE phased 4/7MHz transducer
3DC5-1 motorized convex 1/5MHz 40mm radius transducer
3DEC9-5 motorized microconvex 5/9MHz 10mm radius transducer
IOT7-4 convex 4/7MHz 40mm radius intraoperational transducer
IOJ7-4 linear 4/7MHz 38mm radius intraoperational transducer

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 determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

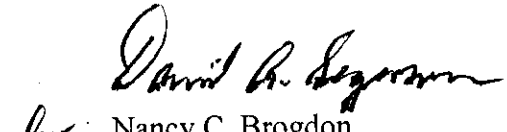
Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

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 contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,



for Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

Prescription Use (Per 221 CFR 801.109)

Ergosonix 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									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		P	P	P		P	P	P	P (*1)	P (*2)
Abdominal		P	P	P	N	P	P	P	P (*1)	P (*2)
Intraoperative (specify)		N	N	N		N	N	N	N (*1)	N (*2)
Intraoperative Neurological		N	N	N		N	N	N	N (*1)	N (*2)
Pediatric		P	P	P	N	P	P	P	P (*1)	P (*2)
Small Organ (specify)		P	P	P		P	P	P	P (*1)	P (*2)
Neonatal Cephalic		P	P	P		P	P	P	P (*1)	P (*2)
Adult Cephalic		P	P	P		P	P	P	P (*1)	P (*2)
Cardiac		N	N	N	N	N	N	N	N (*1)	N (*2)
Transesophageal		N	N	N		N	N	N	N (*1)	N (*2)
Transrectal		P	P	P		P	P	P	P (*1)	P (*2)
Transvaginal		P	P	P		P	P	P	P (*1)	P (*2)
Transurethral										
Intravascular										
Peripheral Vascular		P	P	P		P	P	P	P (*1)	P (*2)
Leparoscopic										
MSK Conventional		P	P	P		P	P	P	P (*1)	P (*2)
MSK Superficial		P	P	P		P	P	P	P (*1)	P (*2)
Other (specify) (*3)		N	N	N		N	N	N	N (*1)	N (*2)

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional Comments:

*1 B/M, B/PWD, B/CWD, B/CFM/PWD, B/AD/PWD, B/DPD/PWD, B/CFM/CWD, B/AD/CWD, B/DPD/CWD
*2 Freehand 3D imaging, live 3D imaging, Directional Power Doppler (DPD)
*3 Transcranial Doppler

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices

K041226

Prescription Use (Per 221 CFR 801.109)

MODULO 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									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		P	P	P		P	P	P	P (*1)	P (*2)
Abdominal		P	P	P	N	P	P	P	P (*1)	P (*2)
Intraoperative (specify)		N	N	N		N	N	N	N (*1)	N (*2)
Intraoperative Neurological		N	N	N		N	N	N	N (*1)	N (*2)
Pediatric		P	P	P	N	P	P	P	P (*1)	P (*2)
Small Organ (specify)		P	P	P		P	P	P	P (*1)	P (*2)
Neonatal Cephalic		P	P	P		P	P	P	P (*1)	P (*2)
Adult Cephalic		P	P	P		P	P	P	P (*1)	P (*2)
Cardiac		N	N	N	N	N	N	N	N (*1)	N (*2)
Transesophageal		N	N	N		N	N	N	N (*1)	N (*2)
Transrectal		P	P	P		P	P	P	P (*1)	P (*2)
Transvaginal		P	P	P		P	P	P	P (*1)	P (*2)
Transurethral										
Intravascular										
Peripheral Vascular		P	P	P		P	P	P	P (*1)	P (*2)
Leparoscopic										
MSK Conventional		P	P	P		P	P	P	P (*1)	P (*2)
MSK Superficial		P	P	P		P	P	P	P (*1)	P (*2)
Other (specify) (*3)		N	N	N		N	N	N	N (*1)	N (*2)

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional Comments:

*1 B/M, B/PWD, B/CWD, B/CFM/PWD, B/AD/PWD, B/DPD/PWD, B/CFM/CWD, B/AD/CWD, B/DPD/CWD
*2 Freehand 3D imaging, live 3D imaging, Directional Power Doppler (DPD)
*3 Transcranial Doppler

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K042326

Prescription Use (Per 221 CFR 801.109)

C5-1 40 convex 1/5MHz 40mm radius transducer

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									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		N	N	N		N	N	N	N (*1)	N (*2)
Abdominal		N	N	N		N	N	N	N (*1)	N (*2)
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		N	N	N		N	N	N	N (*1)	N (*2)
Small Organ (specify)		N	N	N		N	N	N	N (*1)	N (*2)
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		N	N	N		N	N	N	N (*1)	N (*2)
Leparoscopic										
MSK Conventional		N	N	N		N	N	N	N (*1)	N (*2)
MSK Superficial		N	N	N		N	N	N	N (*1)	N (*2)
Other (specify)										

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional Comments:

*1 B/M, B/PWD, B/CWD, B/CFM/PWD, B/AD/PWD, B/DPD/PWD, B/CFM/CWD, B/AD/CWD, B/DPD/CWD
*2 Freehand 3D imaging, Directional Power Doppler (DPD)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Seymour

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K042326

Prescription Use (Per 221 CFR 801.109)

C5-1 60 convex 1/5MHz 60mm radius transducer

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									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		N	N	N		N	N	N	N (*1)	N (*2)
Abdominal		N	N	N		N	N	N	N (*1)	N (*2)
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		N	N	N		N	N	N	N (*1)	N (*2)
Small Organ (specify)		N	N	N		N	N	N	N (*1)	N (*2)
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		N	N	N		N	N	N	N (*1)	N (*2)
Leparoscopic										
MSK Conventional		N	N	N		N	N	N	N (*1)	N (*2)
MSK Superficial		N	N	N		N	N	N	N (*1)	N (*2)
Other (specify)										

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional Comments:

*1 B/M, B/PWD, B/CWD, B/CFM/PWD, B/AD/PWD, B/DPD/PWD, B/CFM/CWD, B/AD/CWD, B/DPD/CWD
*2 Freehand 3D imaging, Directional Power Doppler (DPD)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Seymour

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices

510(k) Number K042326

Prescription Use (Per 221 CFR 801.109)

L12-5 linear 5/12MHz 38mm transducer

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									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		N	N	N		N	N	N	N (*1)	N (*2)
Abdominal		N	N	N		N	N	N	N (*1)	N (*2)
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		N	N	N		N	N	N	N (*1)	N (*2)
Small Organ (specify)		N	N	N		N	N	N	N (*1)	N (*2)
Neonatal Cephalic		N	N	N		N	N	N	N (*1)	N (*2)
Adult Cephalic		N	N	N		N	N	N	N (*1)	N (*2)
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		N	N	N		N	N	N	N (*1)	N (*2)
Leparoscopic										
MSK Conventional		N	N	N		N	N	N	N (*1)	N (*2)
MSK Superficial		N	N	N		N	N	N	N (*1)	N (*2)
Other (specify)										

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional Comments:

*1 B/M, B/PWD, B/CWD, B/CFM/PWD, B/AD/PWD, B/DPD/PWD, B/CFM/CWD, B/AD/CWD, B/DPD/CWD
*2 Freehand 3D imaging, Directional Power Doppler (DPD)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Seymour

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K042336

Prescription Use (Per 221 CFR 801.109)

L12-5W linear 5/12MHz 50mm transducer

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									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		N	N	N		N	N	N	N (*1)	N (*2)
Abdominal		N	N	N		N	N	N	N (*1)	N (*2)
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		N	N	N		N	N	N	N (*1)	N (*2)
Small Organ (specify)		N	N	N		N	N	N	N (*1)	N (*2)
Neonatal Cephalic		N	N	N		N	N	N	N (*1)	N (*2)
Adult Cephalic		N	N	N		N	N	N	N (*1)	N (*2)
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		N	N	N		N	N	N	N (*1)	N (*2)
Leparoscopic										
MSK Conventional		N	N	N		N	N	N	N (*1)	N (*2)
MSK Superficial		N	N	N		N	N	N	N (*1)	N (*2)
Other (specify)										

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional Comments:

*1 B/M, B/PWD, B/CWD, B/CFM/PWD, B/AD/PWD, B/DPD/PWD, B/CFM/CWD, B/AD/CWD, B/DPD/CWD
*2 Freehand 3D imaging, Directional Power Doppler (DPD)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lyerly

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K042336

Prescription Use (Per 221 CFR 801.109)

L9-4 linear 4/9MHz 38mm transducer

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									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		N	N	N		N	N	N	N (*1)	N (*2)
Abdominal		N	N	N		N	N	N	N (*1)	N (*2)
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		N	N	N		N	N	N	N (*1)	N (*2)
Small Organ (specify)		N	N	N		N	N	N	N (*1)	N (*2)
Neonatal Cephalic		N	N	N		N	N	N	N (*1)	N (*2)
Adult Cephalic		N	N	N		N	N	N	N (*1)	N (*2)
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		N	N	N		N	N	N	N (*1)	N (*2)
Leparoscopic										
MSK Conventional		N	N	N		N	N	N	N (*1)	N (*2)
MSK Superficial		N	N	N		N	N	N	N (*1)	N (*2)
Other (specify)										

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional Comments:

*1 B/M, B/PWD, B/CWD, B/CFM/PWD, B/AD/PWD, B/DPD/PWD, B/CFM/CWD, B/AD/CWD, B/DPD/CWD
*2 Freehand 3D imaging, Directional Power Doppler (DPD)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lyerla

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K042326

Prescription Use (Per 221 CFR 801.109)

PA3-2 phased array 2/3MHz transducer

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									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal		N	N	N	N	N	N	N	N (*1)	N (*2)
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		N	N	N	N	N	N	N	N (*1)	N (*2)
Small Organ (specify)										
Neonatal Cephalic		N	N	N		N	N	N	N (*1)	N (*2)
Adult Cephalic		N	N	N		N	N	N	N (*1)	N (*2)
Cardiac		N	N	N	N	N	N	N	N (*1)	N (*2)
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Leparoscopic										
MSK Conventional										
MSK Superficial										
Other (specify) (*3)		N	N	N		N	N	N	N (*1)	N (*2)

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional Comments:

*1 B/M, B/PWD, B/CWD, B/CFM/PWD, B/AD/PWD, B/DPD/PWD, B/CFM/CWD, B/AD/CWD, B/DPD/CWD
*2 Freehand 3D imaging, Directional Power Doppler (DPD)
*3 Transcranial Doppler

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices

510(k) Number K042336

Prescription Use (Per 221 CFR 801.109)

PA4-2 phased array 2/4MHz transducer

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									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal		N	N	N	N	N	N	N	N (*1)	N (*2)
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		N	N	N	N	N	N	N	N (*1)	N (*2)
Small Organ (specify)										
Neonatal Cephalic		N	N	N		N	N	N	N (*1)	N (*2)
Adult Cephalic		N	N	N		N	N	N	N (*1)	N (*2)
Cardiac		N	N	N	N	N	N	N	N (*1)	N (*2)
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Leparoscopic										
MSK Conventional										
MSK Superficial										
Other (specify) (*3)		N	N	N		N	N	N	N (*1)	N (*2)

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional Comments:

*1 B/M, B/PWD, B/CWD, B/CFM/PWD, B/AD/PWD, B/DPD/PWD, B/CFM/CWD, B/AD/CWD, B/DPD/CWD
*2 Freehand 3D imaging, Directional Power Doppler (DPD)
*3 Transcranial Doppler

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Seguin

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices

K01/2326

Prescription Use (Per 221 CFR 801.109)

PA3-2 phased array 2/4MHz transducer

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									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal		N	N	N	N	N	N	N	N (*1)	N (*2)
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		N	N	N	N	N	N	N	N (*1)	N (*2)
Small Organ (specify)										
Neonatal Cephalic		N	N	N		N	N	N	N (*1)	N (*2)
Adult Cephalic		N	N	N		N	N	N	N (*1)	N (*2)
Cardiac		N	N	N	N	N	N	N	N (*1)	N (*2)
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Leparoscopic										
MSK Conventional										
MSK Superficial										
Other (specify) (*3)		N	N	N		N	N	N	N (*1)	N (*2)

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional Comments:

*1 B/M, B/PWD, B/CWD, B/CFM/PWD, B/AD/PWD, B/DPD/PWD, B/CFM/CWD, B/AD/CWD, B/DPD/CWD
*2 Freehand 3D imaging, Directional Power Doppler (DPD)
*3 Transcranial Doppler

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lieberman

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices

K042326

Prescription Use (Per 221 CFR 801.109)

PA7-4 phased array 4/7MHz transducer

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									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal		N	N	N	N	N	N	N	N (*1)	N (*2)
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		N	N	N	N	N	N	N	N (*1)	N (*2)
Small Organ (specify)										
Neonatal Cephalic		N	N	N		N	N	N	N (*1)	N (*2)
Adult Cephalic		N	N	N		N	N	N	N (*1)	N (*2)
Cardiac		N	N	N	N	N	N	N	N (*1)	N (*2)
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Leparoscopic										
MSK Conventional										
MSK Superficial										
Other (specify) (*3)		N	N	N		N	N	N	N (*1)	N (*2)

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional Comments:

*1 B/M, B/PWD, B/CWD, B/CFM/PWD, B/AD/PWD, B/DPD/PWD, B/CFM/CWD, B/AD/CWD, B/DPD/CWD
*2 Freehand 3D imaging, Directional Power Doppler (DPD)
*3 Transcranial Doppler

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David G. Hoyer

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices

K042386

Prescription Use (Per 221 CFR 801.109)

ER7 biplane endocavity 5/9MHz transducer

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									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal		N	N	N		N	N	N	N (*1)	N (*2)
Transvaginal		N	N	N		N	N	N	N (*1)	N (*2)
Transurethral										
Intravascular										
Peripheral Vascular										
Leparoscopic										
MSK Conventional										
MSK Superficial										
Other (specify) (*3)										

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional Comments:

***1** B/M, B/PWD, B/CWD, B/CFM/PWD, B/AD/PWD, B/DPD/PWD, B/CFM/CWD, B/AD/CWD, B/DPD/CWD
***2** Freehand 3D imaging, Directional Power Doppler (DPD)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David G. Lyman

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices

1/24/2006

Prescription Use (Per 221 CFR 801.109)

EC9-5 microconvex endocavity 5/9MHz 10mm radius transducer

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									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal		**N**	**N**	**N**		**N**	**N**	**N**	**N** (*1)	**N** (*2)
Transvaginal		**N**	**N**	**N**		**N**	**N**	**N**	**N** (*1)	**N** (*2)
Transurethral										
Intravascular										
Peripheral Vascular										
Leparoscopic										
MSK Conventional										
MSK Superficial										
Other (specify) (*3)										

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional Comments:

*1 B/M, B/PWD, B/CWD, B/CFM/PWD, B/AD/PWD, B/DPD/PWD, B/CFM/CWD, B/AD/CWD, B/DPD/CWD
*2 Freehand 3D imaging, Directional Power Doppler (DPD)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Seguson

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K042326

Prescription Use (Per 221 CFR 801.109)

MC7 microconvex 5/9MHz 10mm radius transducer

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									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		N	N	N		N	N	N	N (*1)	N (*2)
Abdominal		N	N	N		N	N	N	N (*1)	N (*2)
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		N	N	N		N	N	N	N (*1)	N (*2)
Small Organ (specify)		N	N	N		N	N	N	N (*1)	N (*2)
Neonatal Cephalic		N	N	N		N	N	N	N (*1)	N (*2)
Adult Cephalic		N	N	N		N	N	N	N (*1)	N (*2)
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		N	N	N		N	N	N	N (*1)	N (*2)
Leparoscopic										
MSK Conventional		N	N	N		N	N	N	N (*1)	N (*2)
MSK Superficial		N	N	N		N	N	N	N (*1)	N (*2)
Other (specify) (*3)										

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional Comments:

*1 B/M, B/PWD, B/CWD, B/CFM/PWD, B/AD/PWD, B/DPD/PWD, B/CFM/CWD, B/AD/CWD, B/DPD/CWD

*2 Freehand 3D imaging, Directional Power Doppler (DPD)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lieberman

(Division Sign-Off)
Division of Reproductive, Abdominal, ... Radiological Devices

K042326

Prescription Use (Per 221 CFR 801.109)

L15-8 linear 8/15MHz 29mm transducer

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									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		N	N	N		N	N	N	N (*1)	N (*2)
Abdominal		N	N	N		N	N	N	N (*1)	N (*2)
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		N	N	N		N	N	N	N (*1)	N (*2)
Small Organ (specify)		N	N	N		N	N	N	N (*1)	N (*2)
Neonatal Cephalic		N	N	N		N	N	N	N (*1)	N (*2)
Adult Cephalic		N	N	N		N	N	N	N (*1)	N (*2)
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		N	N	N		N	N	N	N (*1)	N (*2)
Leparoscopic										
MSK Conventional		N	N	N		N	N	N	N (*1)	N (*2)
MSK Superficial		N	N	N		N	N	N	N (*1)	N (*2)
Other (specify) (*3)										

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional Comments:

*1 B/M, B/PWD, B/CWD, B/CFM/PWD, B/AD/PWD, B/DPD/PWD, B/CFM/CWD, B/AD/CWD, B/DPD/CWD
*2 Freehand 3D imaging, Directional Power Doppler (DPD)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David B. Seymour

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices

K043276

Prescription Use (Per 221 CFR 801.109)

C7-4 convex 4/7MHz 40mm radius transducer

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									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		N	N	N		N	N	N	N (*1)	N (*2)
Abdominal		N	N	N		N	N	N	N (*1)	N (*2)
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		N	N	N		N	N	N	N (*1)	N (*2)
Small Organ (specify)		N	N	N		N	N	N	N (*1)	N (*2)
Neonatal Cephalic		N	N	N		N	N	N	N (*1)	N (*2)
Adult Cephalic		N	N	N		N	N	N	N (*1)	N (*2)
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		N	N	N		N	N	N	N (*1)	N (*2)
Leparoscopic										
MSK Conventional		N	N	N		N	N	N	N (*1)	N (*2)
MSK Superficial		N	N	N		N	N	N	N (*1)	N (*2)
Other (specify) (*3)										

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional Comments:

*1 B/M, B/PWD, B/CWD, B/CFM/PWD, B/AD/PWD, B/DPD/PWD, B/CFM/CWD, B/AD/CWD, B/DPD/CWD
*2 Freehand 3D imaging, Directional Power Doppler (DPD)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices

510(k) Number K043326

Prescription Use (Per 221 CFR 801.109)

CC5-1 microconvex 1/5MHz 15mm radius transducer

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									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		N	N	N		N	N	N	N (*1)	N (*2)
Abdominal		N	N	N		N	N	N	N (*1)	N (*2)
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		N	N	N		N	N	N	N (*1)	N (*2)
Small Organ (specify)		N	N	N		N	N	N	N (*1)	N (*2)
Neonatal Cephalic		N	N	N		N	N	N	N (*1)	N (*2)
Adult Cephalic		N	N	N		N	N	N	N (*1)	N (*2)
Cardiac		N	N	N		N	N	N	N (*1)	N (*2)
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		N	N	N		N	N	N	N (*1)	N (*2)
Leparoscopic										
MSK Conventional		N	N	N		N	N	N	N (*1)	N (*2)
MSK Superficial		N	N	N		N	N	N	N (*1)	N (*2)
Other (specify) (*3)										

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional Comments:

*1 B/M, B/PWD, B/CWD, B/CFM/PWD, B/AD/PWD, B/DPD/PWD, B/CFM/CWD, B/AD/CWD, B/DPD/CWD
*2 Freehand 3D imaging, Directional Power Doppler (DPD)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lyman

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices 1/11/2011

Prescription Use (Per 221 CFR 801.109)

T7-4 TEE phased array 4/7MHz transducer

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									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal		**N**	**N**	**N**		**N**	**N**	**N**	**N** (*1)	**N** (*2)
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Leparoscopic										
MSK Conventional										
MSK Superficial										
Other (specify) (*3)										

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional Comments:

*1 B/M, B/PWD, B/CWD, B/CFM/PWD, B/AD/PWD, B/DPD/PWD, B/CFM/CWD, B/AD/CWD, B/DPD/CWD
*2 Freehand 3D imaging, Directional Power Doppler (DPD)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Feigal

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
(ODE) Number K042926

Prescription Use (Per 221 CFR 801.109)

3DC5-1 motorized convex 1/5MHz 40mm radius transducer

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									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		N	N	N		N	N	N	N (*1)	N (*2)
Abdominal		N	N	N		N	N	N	N (*1)	N (*2)
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		N	N	N		N	N	N	N (*1)	N (*2)
Small Organ (specify)		N	N	N		N	N	N	N (*1)	N (*2)
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		N	N	N		N	N	N	N (*1)	N (*2)
Leparoscopic										
MSK Conventional		N	N	N		N	N	N	N (*1)	N (*2)
MSK Superficial		N	N	N		N	N	N	N (*1)	N (*2)
Other (specify) (*3)										

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional Comments:

*1 B/M, B/PWD, B/CWD, B/CFM/PWD, B/AD/PWD, B/DPD/PWD, B/CFM/CWD, B/AD/CWD, B/DPD/CWD
*2 Freehand 3D imaging, Live 3D imaging, Directional Power Doppler (DPD)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K042326

Prescription Use (Per 221 CFR 801.109)

3DEC9-5 motorized microconvex 5/9MHz 10mm radius transducer

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									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		N	N	N		N	N	N	N (*1)	N (*2)
Abdominal		N	N	N		N	N	N	N (*1)	N (*2)
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		N	N	N		N	N	N	N (*1)	N (*2)
Small Organ (specify)		N	N	N		N	N	N	N (*1)	N (*2)
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal		N	N	N		N	N	N	N (*1)	N (*2)
Transvaginal		N	N	N		N	N	N	N (*1)	N (*2)
Transurethral										
Intravascular										
Peripheral Vascular		N	N	N		N	N	N	N (*1)	N (*2)
Leparoscopic										
MSK Conventional		N	N	N		N	N	N	N (*1)	N (*2)
MSK Superficial		N	N	N		N	N	N	N (*1)	N (*2)
Other (specify) (*3)										

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional Comments:

*1 B/M, B/PWD, B/CWD, B/CFM/PWD, B/AD/PWD, B/DPD/PWD, B/CFM/CWD, B/AD/CWD, B/DPD/CWD

*2 Freehand 3D imaging, Live 3D imaging, Directional Power Doppler (DPD)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices K042326

Prescription Use (Per 221 CFR 801.109)

IOT7-4 convex 4/7MHz 40mm radius intraoperational transducer

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									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		N	N	N		N	N	N	N (*1)	N (*2)
Abdominal		N	N	N		N	N	N	N (*1)	N (*2)
Intraoperative (specify)		N	N	N		N	N	N	N (*1)	N (*2)
Intraoperative Neurological		N	N	N		N	N	N	N (*1)	N (*2)
Pediatric		N	N	N		N	N	N	N (*1)	N (*2)
Small Organ (specify)		N	N	N		N	N	N	N (*1)	N (*2)
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal		N	N	N		N	N	N	N (*1)	N (*2)
Transvaginal		N	N	N		N	N	N	N (*1)	N (*2)
Transurethral										
Intravascular										
Peripheral Vascular		N	N	N		N	N	N	N (*1)	N (*2)
Leparoscopic										
MSK Conventional		N	N	N		N	N	N	N (*1)	N (*2)
MSK Superficial		N	N	N		N	N	N	N (*1)	N (*2)
Other (specify) (*3)										

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional Comments:

*1 B/M, B/PWD, B/CWD, B/CFM/PWD, B/AD/PWD, B/DPD/PWD, B/CFM/CWD, B/AD/CWD, B/DPD/CWD
*2 Freehand 3D imaging, Live 3D imaging, Directional Power Doppler (DPD)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K042326

Prescription Use (Per 221 CFR 801.109)

IOJ7-4 linear 4/7MHz 38mm radius intraoperational transducer

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									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		N	N	N		N	N	N	N (*1)	N (*2)
Abdominal		N	N	N		N	N	N	N (*1)	N (*2)
Intraoperative (specify)		N	N	N		N	N	N	N (*1)	N (*2)
Intraoperative Neurological		N	N	N		N	N	N	N (*1)	N (*2)
Pediatric		N	N	N		N	N	N	N (*1)	N (*2)
Small Organ (specify)		N	N	N		N	N	N	N (*1)	N (*2)
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal		N	N	N		N	N	N	N (*1)	N (*2)
Transvaginal		N	N	N		N	N	N	N (*1)	N (*2)
Transurethral										
Intravascular										
Peripheral Vascular		N	N	N		N	N	N	N (*1)	N (*2)
Leparoscopic										
MSK Conventional		N	N	N		N	N	N	N (*1)	N (*2)
MSK Superficial		N	N	N		N	N	N	N (*1)	N (*2)
Other (specify) (*3)										

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional Comments:

*1 B/M, B/PWD, B/CWD, B/CFM/PWD, B/AD/PWD, B/DPD/PWD, B/CFM/CWD, B/AD/CWD, B/DPD/CWD
*2 Freehand 3D imaging, Live 3D imaging, Directional Power Doppler (DPD)

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[illegible] Number K042376