

K061608

HITACHI

Summary of Safety and Effectiveness

Device Description

The Hitachi EUB-5500 Diagnostic Ultrasound Scanner is a Track 3 Diagnostic Ultrasound Pulsed Doppler and Pulsed Echo Imaging System capable of the following operating functions:

- B Mode
- Pulsed Doppler
- Color Flow
- Harmonic imaging
- 3D imaging
- M Mode
- Continuous Wave Doppler
- Amplitude Doppler
- Superficial musculoskeletal imaging
- 4D imaging

NOV 22 2006

Safety

As a Track 3 ultrasound device, the Hitachi EUB-5500 Diagnostic Ultrasound Scanner complies with the *Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment (1992)* – published by NEMA as UD-3.

With respect to limits on acoustic outputs, the Hitachi EUB-5500 Diagnostic Ultrasound Scanner complies with the guideline limits set in the *510(k) Diagnostic Ultrasound Guidance – Revision: April 14, 1994*.

With regard to general safety, the Hitachi EUB-5500 Diagnostic Ultrasound Scanner is designed to comply with *IEC 606601-1 (1998) Medical Electrical Equipment, Part 1 – General Requirements for Safety*.



JUN 21 2007

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Douglas J. Thistlethwaite
Manager of Regulatory Affairs
Hitachi Medical Systems America, Inc.
1959 Summit Commerce Park
TWINSBURG OH 44087

Re: K061608

Trade Name: EUB-5500 Diagnostic Ultrasound Scanner
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 transducer
Regulatory Class: II
Product Code: IYO, IYN, and ITX
Dated: December 1, 2006
Received: December 4, 2006

Dear Mr. Thistlethwaite:

This letter corrects our substantially equivalent letter of November 22, 2006.

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 EUB-5500 Diagnostic Ultrasound Scanner, as described in your premarket notification:

Transducer Model Number

EUP-B314
EUP-B512
EUP-C314G
EUP-C516
EUP-C524
EUP-CC531
EUP-CV524
EUP-F334
EUP- L34T
EUP-L52
EUP-L53
EUP-L53L
EUP-L65
EUP-R53W
EUP-R54AW-19,-33
EUP-S50A
EUP-S52
Fujinon SP711

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 (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>

If you have any questions regarding the content of this letter, please contact John Chen at (240) 276-3666.

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)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: EUB-5500
 Transducer: EUP-B512

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

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	E	E	E		E	E	E
	Abdominal	Ea	Ea	Ea		Ea	Ea	Ea
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Spec.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
Intra-luminal								
Other (spec.)								
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

E = Added under Appendix E

*Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

**Amplitude Doppler, Harmonic Imaging.

Additional Comments:

- Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).
- Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).
- Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.
- Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.
- Subscript "e": Includes imaging for guidance of transrectal biopsy.
- Subscript "f": Includes imaging for guidance of transvaginal biopsy.
- Subscript "g": Includes imaging for guidance of trans-perineal biopsy.
- Subscript "h": Includes imaging for guidance of transrectal biopsy.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K061608

Prescription Use _____
 (Per 21 CFR 801.109)

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DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: EUB-5500
 Transducer: EUP-C314G

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

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	E	E	E		E	E	E
	Abdominal	Ea	Ea	Ea		Ea	Ea	Ea
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	E	E	E		E	E	E
	Small Organ (Spec.)	Ed	Ed	Ed		Ed	Ed	Ed
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
Intra-luminal								
Other (spec.)								
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

E = Added under Appendix E

*Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

**Amplitude Doppler, Harmonic Imaging and 3D Imaging.

Additional Comments:

- Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).
- Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).
- Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.
- Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.
- Subscript "e": Includes imaging for guidance of transrectal biopsy.
- Subscript "f": Includes imaging for guidance of transvaginal biopsy.
- Subscript "g": Includes imaging for guidance of trans-perineal biopsy.
- Subscript "h": Includes imaging for guidance of transrectal biopsy.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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 Division of Reproductive, Abdominal, ENT,
 and Radiological Devices

510(k) Number: K061608

Prescription Use
 (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: EUB-5500
 Transducer: EUP-C524

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

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	E	E	E		E	E	E
	Abdominal	E	E	E		E	E	E
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	E	E	E		E	E	E
	Small Organ (Spec.)	Ec	Ec	Ec		Ec	Ec	Ec
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
Intra-luminal								
Other (spec.)								
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

E = Added under Appendix E

*Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

**Amplitude Doppler, Harmonic Imaging and 3D Imaging.

Additional Comments:

- Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).
- Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).
- Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.
- Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.
- Subscript "e": Includes imaging for guidance of transrectal biopsy.
- Subscript "f": Includes imaging for guidance of transvaginal biopsy.
- Subscript "g": Includes imaging for guidance of trans-perineal biopsy.
- Subscript "h": Includes imaging for guidance of transrectal biopsy.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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 Division of Reproductive, Abdominal, ENT,
 and Radiological Devices

510(k) Number: K061608

Prescription Use ✓
 (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: EUB-5500
 Transducer: EUP-CC531

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

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	E	E	E		E	E	E
	Abdominal							
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Spec.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	Ee	Ee	Ee		Ee	Ee	Ee
	Trans-vaginal	Ef	Ef	Ef		Ef	Ef	Ef
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
Intra-luminal								
Other (spec.)								
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

E = Added under Appendix E

*Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

**Amplitude Doppler, Harmonic Imaging.

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of transrectal biopsy.

Subscript "f": Includes imaging for guidance of transvaginal biopsy.

Subscript "g": Includes imaging for guidance of trans perineal biopsy.

Subscript "h": Includes imaging for guidance of transrectal biopsy.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number: K061608

Prescription Use
(Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: EUB-5500
 Transducer: EUP-CV524

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

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	N	N	N		N	N	N
	Abdominal	N	N	N		N	N	N
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	N	N	N		N	N	N
	Small Organ (Spec.)	Nc	Nc	Nc		Nc	Nc	Nc
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
Intra-luminal								
Other (spec.)								
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N = new indication.

*Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

**Amplitude Doppler, Harmonic Imaging and 3D Imaging.

Additional Comments:

- Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).
- Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).
- Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.
- Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.
- Subscript "e": Includes imaging for guidance of transrectal biopsy.
- Subscript "f": Includes imaging for guidance of transvaginal biopsy.
- Subscript "g": Includes imaging for guidance of trans-perineal biopsy.
- Subscript "h": Includes imaging for guidance of transrectal biopsy.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K061608

Prescription Use
 (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: EUB-5500
 Transducer: EUP-F334

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

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Spec.)	Eb	Eb	Eb		Eb	Eb	Eb
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	E	E	E		E	E	E
	Small Organ (Spec.)	Ec	Ec	Ec		Ec	Ec	Ec
	Neonatal Cephalic	E	E	E		E	E	E
	Adult Cephalic							
	Trans-rectal	E	E	E		E	E	E
	Trans-vaginal	E	E	E		E	E	E
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	E	E	E		E	E	E
	Other (spec.)							

E = Added under Appendix E

*Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

**Amplitude Doppler, Harmonic Imaging.

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of transrectal biopsy.

Subscript "f": Includes imaging for guidance of transvaginal biopsy.

Subscript "g": Includes imaging for guidance of trans-perineal biopsy.

Subscript "h": Includes imaging for guidance of transrectal biopsy.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K061608

Prescription Use
 (Per 21 CFR 801.109)

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DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: EUB-5500
 Transducer: EUP-L34T

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

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	Ea	Ea	Ea		Ea	Ea	Ea
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	E	E	E		E	E	E
	Small Organ (Spec.)	Ed	Ed	Ed		Ed	Ed	Ed
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)	E	E	E		E	E	E
	Musculo-skel. (Superfic.)	E	E	E		E	E	E
Intra-luminal								
Other (spec.)								
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	E	E	E		E	E	E
	Other (spec.)							

E = Added under Appendix E

*Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

**Amplitude Doppler, Harmonic Imaging.

Additional Comments:

- Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).
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- Subscript "e": Includes imaging for guidance of transrectal biopsy.
- Subscript "f": Includes imaging for guidance of transvaginal biopsy.
- Subscript "g": Includes imaging for guidance of trans-perineal biopsy.
- Subscript "h": Includes imaging for guidance of transrectal biopsy.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K061608

Prescription Use _____
 (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: EUB-5500
 Transducer: EUP-L52

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

Clinical Application		Mode of Operation							
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)	
Ophthalmic	Ophthalmic								
	Fetal								
	Abdominal	Ea	Ea	Ea		Ea	Ea	Ea	
	Intra-operative (Spec.)								
	Intra-operative (Neuro.)								
	Laparoscopic								
	Pediatric	E	E	E		E	E	E	
	Small Organ (Spec.)	Ed	Ed	Ed		Ed	Ed	Ed	
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Fetal Imaging & Other	Musculo-skel. (Convent.)	E	E	E		E	E	E
Musculo-skel. (Superfic.)									
Intra-luminal									
Other (spec.)									
Cardiac		Cardiac Adult							
		Cardiac Pediatric							
		Trans-esophageal (card.)							
		Other (spec.)							
Peripheral Vessel		Peripheral vessel	E	E	E		E	E	E
		Other (spec.)							

E = Added under Appendix E

*Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

**Amplitude Doppler. Harmonic Imaging.

Additional Comments:

- Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).
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- Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.
- Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.
- Subscript "e": Includes imaging for guidance of transrectal biopsy.
- Subscript "f": Includes imaging for guidance of transvaginal biopsy.
- Subscript "g": Includes imaging for guidance of trans-perineal biopsy.
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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K001609

Prescription Use
 (Per 21 CFR 801.109)

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DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: EUB-5500
 Transducer: EUP-L53

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

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	Ea	Ea	Ea		Ea	Ea	Ea
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	E	E	E		E	E	E
	Small Organ (Spec.)	Ed	Ed	Ed		Ed	Ed	Ed
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)	E	E	E		E	E	E
	Musculo-skel. (Superfic.)	E	E	E		E	E	E
Intra-luminal								
Other (spec.)								
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	E	E	E		E	E	E
	Other (spec.)							

E = Added under Appendix E

*Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

**Amplitude Doppler, Harmonic Imaging and 3D Imaging.

Additional Comments:

- Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).
- Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).
- Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.
- Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.
- Subscript "e": Includes imaging for guidance of transrectal biopsy.
- Subscript "f": Includes imaging for guidance of transvaginal biopsy.
- Subscript "g": Includes imaging for guidance of trans-perineal biopsy.
- Subscript "h": Includes imaging for guidance of transrectal biopsy.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K061608

Prescription Use
 (Per 21 CFR 801.109)

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DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: EUB-5500
 Transducer: EUP-L53L

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

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	E	E	E		E	E	E
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	E	E	E		E	E	E
	Small Organ (Spec.)	Ec	Ec	Ec		Ec	Ec	Ec
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)	E	E	E		E	E	E
	Musculo-skel. (Superfic.)	E	E	E		E	E	E
Intra-luminal								
Other (spec.)								
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	E	E	E		E	E	E
	Other (spec.)							

E = Added under Appendix E

*Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

**Amplitude Doppler, Harmonic Imaging.

Additional Comments:

- Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).
- Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).
- Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.
- Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.
- Subscript "e": Includes imaging for guidance of transrectal biopsy.
- Subscript "f": Includes imaging for guidance of transvaginal biopsy.
- Subscript "g": Includes imaging for guidance of trans-perineal biopsy.
- Subscript "h": Includes imaging for guidance of transrectal biopsy.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K061608

Prescription Use
 (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: EUB-5500
 Transducer: EUP-L65

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

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	E	E	E		E	E	E
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	E	E	E		E	E	E
	Small Organ (Spec.)	Ec	Ec	Ec		Ec	Ec	Ec
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)	E	E	E		E	E	E
	Musculo-skel. (Superfic.)	E	E	E		E	E	E
Intra-luminal								
Other (spec.)								
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	E	E	E		E	E	E
	Other (spec.)							

E = Added under Appendix E

*Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

**Amplitude Doppler, Harmonic Imaging.

Additional Comments:

- Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).
- Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).
- Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.
- Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.
- Subscript "e": Includes imaging for guidance of transrectal biopsy.
- Subscript "f": Includes imaging for guidance of transvaginal biopsy.
- Subscript "g": Includes imaging for guidance of trans-perineal biopsy.
- Subscript "h": Includes imaging for guidance of transrectal biopsy.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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 Division of Reproductive, Abdominal, ENT,
 and Radiological Devices

510(k) Number: K061608

Prescription Use
 (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: EUB-5500
 Transducer: EUP-R53W

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

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Spec.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	E	E	E		E	E	E
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
Intra-luminal								
Other (spec.)								
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

E = Added under Appendix E

*Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

**Amplitude Doppler, Harmonic Imaging.

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of transrectal biopsy.

Subscript "f": Includes imaging for guidance of transvaginal biopsy.

Subscript "g": Includes imaging for guidance of transperineal biopsy.

Subscript "h": Includes imaging for guidance of transrectal biopsy.

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Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number: K060608

Prescription Use ✓
(Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: EUB-5500
 Transducer: EUP-R54AW-19, -33

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

Clinical Application		Mode of Operation							
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)	
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intra-operative (Spec.)								
	Intra-operative (Neuro.)								
	Laparoscopic								
	Pediatric								
	Small Organ (Spec.)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal		E	E	E		E	E	E
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skel. (Convent.)								
	Musculo-skel. (Superfic.)								
Intra-luminal									
Other (spec.)									
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Trans-esophageal (card.)								
	Other (spec.)								
Peripheral Vessel	Peripheral vessel								
	Other (spec.)								

E = Added under Appendix E

*Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

**Amplitude Doppler, Harmonic Imaging.

Additional Comments:

- Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).
- Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).
- Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.
- Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.
- Subscript "e": Includes imaging for guidance of transrectal biopsy.
- Subscript "f": Includes imaging for guidance of transvaginal biopsy.
- Subscript "g": Includes imaging for guidance of trans-perineal biopsy.
- Subscript "h": Includes imaging for guidance of transrectal biopsy.

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 and Radiological Devices

510(k) Number: K061608

Prescription Use ✓
 (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: EUB-5500
 Transducer: EUP-S50A

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

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	E	E	E	E	E	E	E
	Abdominal	E	E	E	E	E	E	E
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	E	E	E	E	E	E	E
	Small Organ (Spec.)							
	Neonatal Cephalic							
	Adult Cephalic	E	E	E	E	E	E	E
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
Intra-luminal								
Other (spec.)								
Cardiac	Cardiac Adult	E	E	E	E	E	E	E
	Cardiac Pediatric	E	E	E	E	E	E	E
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	E	E	E	E	E	E	E
	Other (spec.)							

E = Added under Appendix E

*Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

**Amplitude Doppler. Harmonic Imaging.

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of transrectal biopsy.

Subscript "f": Includes imaging for guidance of transvaginal biopsy.

Subscript "g": Includes imaging for guidance of trans-perineal biopsy.

Subscript "h": Includes imaging for guidance of transrectal biopsy.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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Division of Reproductive, Abdominal, ENT,
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510(k) Number:

K061608

Prescription Use
(Per 21 CFR 801.109)

150

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: EUB-5500
 Transducer: EUP-S52

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

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	E	E	E	E	E	E	E
	Small Organ (Spec.)	Ec	Ec	Ec	Ec	Ec	Ec	Ec
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
Intra-luminal								
Other (spec.)								
Cardiac	Cardiac Adult							
	Cardiac Pediatric	E	E	E	E	E	E	E
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

E = Added under Appendix E

*Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

**Amplitude Doppler, Harmonic Imaging.

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of transrectal biopsy.

Subscript "f": Includes imaging for guidance of transvaginal biopsy.

Subscript "g": Includes imaging for guidance of transperineal biopsy.

Subscript "h": Includes imaging for guidance of transrectal biopsy.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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 Division of Reproductive, Abdominal, ENT,
 and Radiological Devices

510(k) Number: K061608

Prescription Use _____
 (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: EUB-5500
 Transducer: Fujinon SP711

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

Clinical Application		Mode of Operation							
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)	
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intra-operative (Spec.)								
	Intra-operative (Neuro.)								
	Laparoscopic								
	Pediatric								
	Small Organ (Spec.)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skel. (Convent.)								
	Musculo-skel. (Superfic.)								
Intra-luminal		E							
Other (spec.)									
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Trans-esophageal (card.)								
	Other (spec.)								
Peripheral Vessel	Peripheral vessel								
	Other (spec.)								

E = Added under Appendix E

*Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

**Amplitude Doppler, Harmonic Imaging.

Additional Comments:

- Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).
- Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).
- Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.
- Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy.
- Subscript "e": Includes imaging for guidance of transrectal biopsy.
- Subscript "f": Includes imaging for guidance of transvaginal biopsy.
- Subscript "g": Includes imaging for guidance of trans-perineal biopsy.
- Subscript "h": Includes imaging for guidance of transrectal biopsy.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: 6061608

Prescription Use
 (Per 21 CFR 801.109)