

MAR 29 2000

SUMMARY OF SAFETY AND EFFECTIVENESS
Hitachi EUB-6000 Ultrasound Diagnostic Scanner

Device Description

The Hitachi EUB-6000 Ultrasound Diagnostic Scanner is a Track 3 diagnostic ultrasound pulsed Doppler and pulsed echo imaging system capable of the following operating modes: B (including harmonic imaging), M, Pulsed and Continuous Doppler, and Color Flow (including Amplitude Doppler). It is intended for general ultrasound imaging of the human body, with specific uses under the general applications of cardiac, peripheral vessel, and fetal imaging and other.

Safety

As a Track 3 ultrasound device, the Hitachi EUB-6000 Ultrasound Diagnostic Scanner complies 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 Hitachi EUB-6000 Ultrasound Diagnostic Scanner complies with the guideline limits set in the April 14, 1994, Revision of 510(k) Diagnostic Ultrasound Guidance.

With regard to general safety, the Hitachi EUB-6000 Ultrasound Diagnostic Scanner is designed to comply with IEC 601-1 (1988) Medical Electrical Equipment, Part 1, General Requirements for Safety.



MAR 29 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Charles F. Hottinger, Ph.D.
Director, Regulatory Affairs
Hitachi Medical Corporation of America
Hitachi Medical Systems
660 White Plains Road
Tarrytown, NY 10591-5107

Re: K994026
Hitachi EUB-6000 Ultrasound Diagnostic Device
Regulatory Class: II
Product Code: 90 IYN/21 CFR 892.1550 and 90 IYO/21 CFR 892.1560
Dated: February 25, 2000
Received: February 29, 2000

Dear Dr. Hottinger:

We have reviewed your Section 510(k) 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 Hitachi EUB-6000 Ultrasound Diagnostic Device, as described in your premarket notification:

Transducer Model Numbers

EUP-B314, EUP-C314G, EUP-ES322, EUP-ES52M
EUP-ES533, EUP-F531, EUP-L34T, EUP-L53S, EUP-OL334
EUP-R53W, EUP-S31T, EUP-TC3, EUP-U533 and EUP-V53W

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic QS inspections, the FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification does not affect any obligation you may have under sections 531 and 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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:

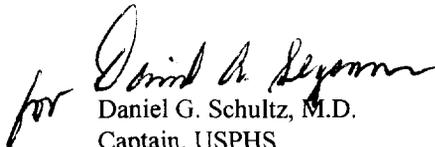
Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

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 and additionally 809.10 for in vitro diagnostic devices), 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 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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 

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: EUB-6000

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	N
	Abdominal	Na	Na	Na	Na	Na	Na	Na
	Intra-operative (Spec.)	Nb	Nb	Nb		Nb	Nb	Nb
	Intra-operative (Neuro.)	N	N	N		N	N	N
	Laparoscopic	N	N	N		N	N	N
	Pediatric	N	N	N	N	N	N	N
	Small Organ (Spec.)	Nd	Nd	Nd		Nd	Nd	Nd
	Neonatal Cephalic	N	N	N		N	N	N
	Adult Cephalic	N	N	N	N	N	N	N
	Trans-rectal	Nh	Nh	Nh		Nh	Nh	Nh
	Trans-vaginal	Nf	Nf	Nf		Nf	Nf	Nf
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)	N	N	N		N	N	N
	Musculo-skel. (Superfic.)	N	N	N		N	N	N
Intra-luminal								
Other (spec.)								
Cardiac	Cardiac Adult	N	N	N	N	N	N	N
	Cardiac Pediatric	N	N	N	N	N	N	N
	Trans-esophageal (card.)	Ng	Ng	Ng		Ng	Ng	Ng
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	N	N	N	N	N	N	N
	Other (spec.)							

N= new indication.

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

** Amplitude Doppler and 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, and 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 pediatric patients.
- 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)

David A. Segman
(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number: K994026

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: EUB-6000
 Transducer: EUP-B314

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	Na	Na	Na		Na	Na	Na
	Intra-operative (Spec.)	Nb	Nb	Nb		Nb	Nb	Nb
	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.)							

N= new indication.

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

** Amplitude Doppler and 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, and 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 pediatric patients.
- Subscript "h": Includes imaging for guidance of transrectal biopsy.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David C. Seymour
 (Division Sign-Off)

Division of Reproductive, Abdominal, ENT,
 and Radiological Devices

510(k) Number: K994026

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: EUB-6000
 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	N	N	N		N	N	N
	Abdominal	Na	Na	Na		Na	Na	Na
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	N	N	N		N	N	N
	Small Organ (Spec.)	Nd	Nd	Nd		Nd	Nd	Nd
	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

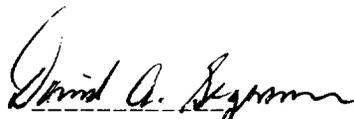
** Amplitude Doppler and Harmonic Imaging

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, and 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 pediatric patients.
- 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: K994026

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: EUB-6000
 Transducer: EUP-ES322

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								
Other (spec.)								
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)	N	N	N		N	N	N
	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 and 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, and 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 pediatric patients.
- Subscript "h": Includes imaging for guidance of transrectal biopsy.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Leggett
 (Division Sign-Off)

Division of Reproductive, Abdominal, ENT,
 and Radiological Devices

510(k) Number: K994026

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: EUB-6000
 Transducer: EUP-ES52M

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								
Other (spec.)								
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)	N	N	N	N	N	N	N
	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 and 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, and 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 pediatric patients.
- Subscript "h": Includes imaging for guidance of transrectal biopsy.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Segerson
 (Division Sign-Off)

Division of Reproductive, Abdominal, ENT,
 and Radiological Devices

510(k) Number: K994026

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: EUB-6000
 Transducer: EUP-ES533

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								
Other (spec.)								
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)	Ng	Ng	Ng		Ng	Ng	Ng
	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 and 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, and 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 pediatric patients.
- Subscript "h": Includes imaging for guidance of transrectal biopsy.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Seymour
 (Division Sign-Off)

Division of Reproductive, Abdominal, ENT,
 and Radiological Devices

510(k) Number: K994026

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: EUB-6000
 Transducer: EUP-F531

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	N	N	N		N	N	N
	Intra-operative (Spec.)	Nb	Nb	Nb		Nb	Nb	Nb
	Intra-operative (Neuro.)	N	N	N		N	N	N
	Laparoscopic							
	Pediatric	N	N	N		N	N	N
	Small Organ (Spec.)	Nc	Nc	Nc		Nc	Nc	Nc
	Neonatal Cephalic	N	N	N		N	N	N
	Adult Cephalic							
	Trans-rectal	N	N	N		N	N	N
	Trans-vaginal	N	N	N		N	N	N
	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	N	N	N		N	N	N
	Other (spec.)							

N= new indication.

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

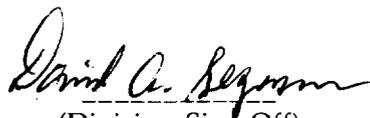
** Amplitude Doppler and Harmonic Imaging

Additional Comments:

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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: K994026

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: EUB-6000
 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	Na	Na	Na		Na	Na	Na
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)	N	N	N		N	N	N
	Laparoscopic							
	Pediatric	N	N	N		N	N	N
	Small Organ (Spec.)	Nd	Nd	Nd		Nd	Nd	Nd
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)	N	N	N		N	N	N
	Musculo-skel. (Superfic.)	N	N	N		N	N	N
Intra-luminal								
Other (spec.)								
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	N
	Other (spec.)							

N= new indication.

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

** Amplitude Doppler and 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, and penis.
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- Subscript "f": Includes imaging for guidance of transvaginal biopsy.
- Subscript "g": Includes pediatric patients.
- Subscript "h": Includes imaging for guidance of transrectal biopsy.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Johnson
 (Division Sign-Off)

Division of Reproductive, Abdominal, ENT,
 and Radiological Devices

510(k) Number: K994026

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: EUB-6000
 Transducer: EUP-L53S

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	Na	Na	Na		Na	Na	Na
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)	N	N	N		N	N	N
	Laparoscopic							
	Pediatric	N	N	N		N	N	N
	Small Organ (Spec.)	Nd	Nd	Nd		Nd	Nd	Nd
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)	N	N	N		N	N	N
	Musculo-skel. (Superfic.)	N	N	N		N	N	N
Intra-luminal								
Other (spec.)								
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	N
	Other (spec.)							

N= new indication.

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

** Amplitude Doppler and 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, and 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 pediatric patients.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Ferguson
 (Division Sign-Off)

Division of Reproductive, Abdominal, ENT,
 and Radiological Devices

510(k) Number: K994026

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: EUB-6000
 Transducer: EUP-OL334

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	N	N	N		N	N	N
	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.)							

N= new indication.

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

** Amplitude Doppler and 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, and penis.
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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 pediatric patients.
- Subscript "h": Includes imaging for guidance of transrectal biopsy.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David C. Seymour
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Division of Reproductive, Abdominal, ENT,
 and Radiological Devices

510(k) Number: K994026

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: EUB-6000
 Transducer: EUP-R53W

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

General (Track I only)	Clinical Application Specific (Tracks I & III)	Mode of Operation						
		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		N	N	N		N	N
	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 and 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, and penis.

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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 pediatric patients.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Segerson
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Division of Reproductive, Abdominal, ENT,
 and Radiological Devices

510(k) Number: K994026

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: EUB-6000
 Transducer: EUP-S31T

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	N
	Abdominal	N	N	N	N	N	N	N
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	N	N	N	N	N	N	N
	Small Organ (Spec.)							
	Neonatal Cephalic							
	Adult Cephalic	N	N	N	N	N	N	N
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
Musculo-skel. (Superfic.)								
Intra-luminal								
Other (spec.)								
Cardiac	Cardiac Adult	N	N	N	N	N	N	N
	Cardiac Pediatric	N	N	N	N	N	N	N
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	N	N	N	N	N	N	N
	Other (spec.)							

N= new indication.

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

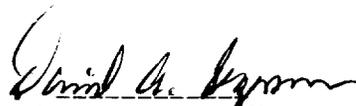
** Amplitude Doppler and Harmonic Imaging

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).
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- 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 pediatric patients.
- Subscript "h": Includes imaging for guidance of transrectal biopsy.

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Division of Reproductive, Abdominal, ENT,
 and Radiological Devices

510(k) Number: K994026

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: EUB-6000
 Transducer EUP-TC3

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								
Other (spec.)								
Cardiac	Cardiac Adult				N			
	Cardiac Pediatric				N			
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel				N			
	Other (spec.)							

N= new indication.

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

** Amplitude Doppler and 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).
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- Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy
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- Subscript "f": Includes imaging for guidance of transvaginal biopsy.
- Subscript "g": Includes pediatric patients.
- Subscript "h": Includes imaging for guidance of transrectal biopsy.

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Division of Reproductive, Abdominal, ENT,
 and Radiological Devices

510(k) Number: K994026

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: EUB-6000
 Transducer: EUP-U533

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		Nh	Nh	Nh		Nh	Nh	Nh
	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 and Harmonic Imaging

Additional Comments:

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David A. Segerson
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Division of Reproductive, Abdominal, ENT,
 and Radiological Devices

510(k) Number: K994026

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: EUB-6000
 Transducer: EUP-V53W

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							
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Spec.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	Ne	Ne	Ne		Ne	Ne	Ne
	Trans-vaginal	Nf	Nf	Nf		Nf	Nf	Nf
	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.

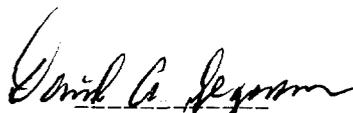
** Amplitude Doppler and Harmonic Imaging

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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: K994026