K040596

MAR 31 2004

510(k) Summary

The following 510(k) summary has been prepared pursuant to requirements specified in 21CFR¶807.92(a).

807.92(a)(1)

Submitter Information

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Contact Person: Carri Graham

Date: February 20, 2004

807.92(a)(2)

Trade Name: 7300 Ultrasound Imaging System

Common Name: Ultrasound Imaging System

Classification Name(s): Ultrasonic pulse doppler imaging system 892.1550
Ultrasonic pulsed echo imaging system 892.1560

Classification Number: 90IYN; 90IYO

807.92(a)(3)

Predicate Device(s)

Esaote, S.p.A.	7250 Ultrasound Imaging System	K982444
Esaote, S.p.A.	7250 Ultrasound Imaging System	K994369
Esaote, S.p.A.	Technos Ultrasound Imaging System	K014168
Philips Medical Systems	M2540 Ultrasound System	K014191

807.92 (a)(4)

Device Description

The 7300 is a compact ultrasound system used to perform diagnostic general ultrasound studies. Its primary modes of operation are: B-Mode, M-Mode, Doppler and Color Flow Mapping and, on lower frequency probes, Tissue Enhancement Imaging (TEI). The 7300 is equipped with an LCD Color Display. The full alphanumeric keyboard allows complete on-screen data entry of patient information and on-screen annotations.
The 7300 can drive phased (PA), convex (CA) and linear array (LA) probes.
The 7300 is equipped with a CD-RW disk drive that can be used for image storage. Data can also be stored directly to a Personal Computer via a LAN port. Optional accessory devices available for the 7300 include an S-VHS video recorder; a monochrome or color page printer and a mobile trolley equipped with an isolation transformer.

807.92(a)(5)

Intended Use(s)

Esaote's Model 7300 is a compact ultrasound system used to perform diagnostic general ultrasound studies including Cardiac, Transesophageal, Peripheral Vascular, Neonatal Cephalic, Adult Cephalic, Small organ, Musculoskeletal (Conventional and Superficial), Abdominal, Fetal, Transvaginal, Transrectal and Pediatric.

807.92(a)(6)

Technological Characteristics

	7300 (This submission)	**Megas (K982444 & 994369)**
Electrical Safety	IEC60601-1	IEC60601-1
Ultrasound Safety	Track 3 (Acoustic Output Display)	Track 3 (Acoustic Output Display)
Indication for Use		
• Cardiac	YES	YES
• Transesophageal	YES	YES
• Peripheral Vascular	YES	YES
• Neonatal Cephalic	YES	YES
• Adult Cephalic	YES	YES
• Small organ	YES	YES
• Musculoskeletal (conventional & superficial)	YES	NO
• Abdominal	YES	YES
• OB/Fetal	YES	YES
• Transvaginal	YES	YES
• Transrectal	YES	YES
• Pediatric	YES	YES
Probe Technology		
• Annular Array	NO	YES
• Phased Array	YES	YES
• Linear array	YES	YES
• Convex Array	YES	YES
Modes of operation	2D, M-Mode, PW, CW, CFM, Amplitude Doppler, TEI	2D, M-Mode, PW, CW, CFM, Amplitude Doppler, TEI
Imaging Frequencies	2.0,2.5, 3.5, 5.0, 7.5, 10 MHz	2.0,2.5, 3.5, 5.0, 7.5, 10 MHz
CFM/Doppler Frequencies	2.0, 2.5, 3.3, 5.0 MHz	2.0, 2.5, 3.3, 5.0 MHz
Tissue Velocity Mapping feature	YES	NO
Biopsy Guidance	YES	YES
• Biopsy Intended Uses	General Purpose, Transrectal, Transvaginal	General Purpose, Transrectal, Transvaginal
• Biopsy Line Depth marker	1 cm	1 cm
Needle Guide Angle	ABS421: 20° 30° ABS523: 45° ABS123: 3.8°	ABS421: 20° 30° ABS523: 45° ABS123: 3.8°
Display Type	SVGA	SVGA
Digital Archival Capabilities	YES	YES
DICOM Classes: Media Storage, Storage SCU	YES	YES
VCR / Page Printer	YES	YES
M&A Capabilities	Cardiac, Vascular, OB and general purpose measurements	Cardiac, Vascular, OB and general purpose measurements
Weight	10 kg	25 kg
Dimensions	portable position: 35.5 (w) x 14 (h) x 49 (d) cm use position: 35.5 (w) x 41 (h) x 49 (d) cm	portable position: 46 (w) x 23.5 (h) x 55 (d) cm use position: 46 (w) x 23.5 (h) x 68 (d) cm

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 31 2004

Esaote, S.p.A.
% Ms. Carri Graham
The Anson Group, LLC
7992 Castleway Drive
INDIANAPOLIS IN 46250

Re: K040596
Trade Name: 7300 Ultrasound Imaging System
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: 90 IYN, IYO, and ITX
Dated: March 5, 2004
Received: March 8, 2004

Dear Ms. Graham:

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 7300 Ultrasound Imaging System, as described in your premarket notification:

Transducer Model Number

PA230E
PA122E
LA523
CA421

EC123
TE022

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

Enclosures

Diagnostic Ultrasound Indications for Use Form

Mod.7300

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

	Mode of Operation									
Clinical Application	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify) TEI (3)
Ophthalmic										
Fetal		N	N	N		N	N		N [2]	N
Abdominal		N	N	N		N	N		N [2]	N
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		N	N	N	N	N	N		N [2]	N
Small Organ (specify) [1]		N	N	N	N	N	N		N [2]	
Neonatal Cephalic		N	N	N	N	N	N		N [2]	
Adult Cephalic		N	N	N	N	N	N		N [2]	
Cardiac		N	N	N	N	N			N [2]	N
Transesophageal		N	N	N	N	N			N [2]	
Transrectal		N	N	N		N	N		N [2]	
Transvaginal		N	N	N		N	N		N [2]	
Transurethral										
Intravascular										
Peripheral Vascular		N	N	N	N	N	N		N [2]	
Laparoscopic										
Musculo-skeletal Conventional		N	N	N	N	N	N		N [2]	
Musculo-skeletal Superficial		N	N	N	N	N	N		N [2]	
Other (specify)										

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

Additional Comments:

[1] Small organs include Thyroid, Breast and Testicles.

[2] Applicable combined modes: B+M+PW+CW+CFM+PD

[3] Tissue Enhancement Imaging (TEI)

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

concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A. Seymour

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K040596

Diagnostic Ultrasound Indications for Use Form

Transducer: **PA230E**

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

	Mode of Operation									
Clinical Application	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify) TEI (2)
Ophthalmic										
Fetal										
Abdominal		N	N	N	N	N	N		N[1]	
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic		N	N	N	N	N	N		N [1]	
Cardiac		N	N	N	N	N	N		N [1]	N
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculoskeletal Superficial										
Other (specify)										

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

Additional Comments:

[1] Applicable combined modes: B+M+PW+CW+CFM+PD
[2] Tissue Enhancement Imaging (TEI)

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concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David R. Lyman

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K040596

Diagnostic Ultrasound Indications for Use Form

Transducer: **PA122E**

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

	Mode of Operation									
Clinical Application	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		N	N	N	N	N	N		N[1]	
Small Organ (specify)										
Neonatal Cephalic		N	N	N	N	N	N		N[1]	
Adult Cephalic										
Cardiac		N	N	N	N	N			N[1]	
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		N	N	N	N	N	N		N[1]	
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

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

Additional Comments:

[1] Applicable combined modes: B+M+PW+CW+CFM+PD

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Prescription Use (Per 21 CFR 801.109)

David A. Feigman

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K040596

Diagnostic Ultrasound Indications for Use Form

Transducer: **LA523**

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

	Mode of Operation									
Clinical Application	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		N	N	N		N	N		N[2]	
Small Organ (specify) [1]		N	N	N		N	N		N[2]	
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		N	N	N		N	N		N[2]	
Laparoscopic										
Musculo-skeletal Conventional		N	N	N		N	N		N[2]	
Musculo-skeletal Superficial		N	N	N		N	N		N[2]	
Other (specify)										

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

Additional Comments:

[1] Small organs include Thyroid, Breast and Testicles.

[2] Applicable combined modes: B+M+PW+CW+CFM+PD

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Prescription Use (Per 21 CFR 801.109)

David A. Bysom

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K040596

Diagnostic Ultrasound Indications for Use Form

Transducer: **CA421**

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

	Mode of Operation									
Clinical Application	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify) TEI (2)
Ophthalmic										
Fetal		N	N	N		N	N		N[1]	N
Abdominal		N	N	N		N	N		N[1]	N
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		N	N	N		N	N		N[1]	N
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

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

Additional Comments:

[1] Applicable combined modes: B+M+PW+CFM+PD.

[2] Tissue Enhancement Imaging (TEI)

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concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A. Seymour

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

510(k) Number K040596

Diagnostic Ultrasound Indications for Use Form

Transducer: **EC123**

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

	Mode of Operation									
Clinical Application	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[1]	
Transvaginal		N	N	N		N	N		N[1]	
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal										
Conventional										
Musculoskeletal Superficial										
Other (specify)										

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

Additional Comments:

[1] Applicable combined modes: B+M+PW+CFM+PD.

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Prescription Use (Per 21 CFR 801.109)

David A. Lynn

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

510(k) Number K040596

Diagnostic Ultrasound Indications for Use Form

Transducer: **TE022**

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

	Mode of Operation									
Clinical Application	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[1]	
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal										
Conventional										
Musculoskeletal Superficial										
Other (specify)										

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

Additional Comments:

[1] Applicable combined modes: B+M+PW++CW+CFM+PD

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concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A. Lagorio

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K040596