K 052805

OCT 17 2005

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

Carri Graham, Official Correspondent
The Anson Group
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Contact Person: Carri Graham

Date: September 29, 2005

807.92(a)(2)

Trade Name: MyLab30, 50, 70 Systems

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)

K040596	7300 (MyLab30)	Esaote, S.p.A.
K050326	7350 (MyLab50)	Esaote, S.p.A.
K051308	6150 (MyLab70)	Esaote, S.p.A.
K051837	6100 (MyLab90)	Esaote, S.p.A.

807.92 (a)(4)

Device Description

The 7300 (MyLab30), 7350 (MyLab50) and 6150 (MyLab70) system designs remain the same as those previously cleared by FDA via K040596, K050326, and K051308, respectively. They are compact ultrasound systems used to perform diagnostic general ultrasound studies. Their primary modes of operation are: B-Mode, M-Mode, Doppler and Color Flow Mapping and, on lower frequency probes, Tissue Enhancement Imaging (TEI). The systems are equipped with an LCD Color Display and can drive phased (PA), convex (CA) and linear array (LA) and Doppler probes.

The 7300 (MyLab30), 7350 (MyLab50) and 6150 (MyLab70) models are manufactured under an ISO 9001:2000 and ISO 13485 certified quality system.

807.92(a)(5)

Intended Use(s)

Esaote's Model 7300 (MyLab30) 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, Pediatric and Intraoperative Abdominal.

Esaote's Model 7350 (MyLab50) is a mainframe 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, Pediatric and Intraoperative Abdominal.

Esaote's Model 6150 (MyLab70) is a mainframe 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, Pediatric Other: Urological, and Intraoperative Abdominal.

807.92(a)(6)

Technological Characteristics

To be added via this 510(k)	MyLab90 (6100) K051837 (Predicate)	MyLab30CV (7300) K040596	MyLab50 (7350) K050326	MyLab70 (6150) K051308
Doppler Probes				
- 2.0 CW	✓	YES	✓	✓
- 5.0 CW	✓	YES	✓	✓
IOE Probe				
- IOE323	✓	YES	YES	YES
Biopsy Attachment				
- ABS15	✓	YES	YES	YES
VPAN	✓	YES	YES	✓
Compound Imaging	✓	YES	YES	YES
Intelligent Real Time Processing	✓	NO	NO	YES
Intraoperative Abdominal Indication for Use	✓	YES	YES	YES

✓ Indicates that the system has been previously cleared for that item
YES Indicates that the item is to be cleared via this submission
NO Indicates that the item is NOT to be cleared via this submission

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 17 2005

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

Re: K052805
Trade Name: Model 7300 (MyLab30), Model 7350 (MyLab50), and Model 6150 (MyLab70) Ultrasound Imaging Systems
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: IYN, IYO, and ITX
Dated: September 29, 2005
Received: October 4, 2005

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 Model 7300 (MyLab30), Model 7350 (MyLab50), and Model 6150 (MyLab70) Ultrasound Imaging Systems, as described in your premarket notification:

Transducer Model Number

IOE323
2 CW
5 CW

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 (301) 443-6597 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 Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

Nancy C. Brogdon

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

Model 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)
Ophthalmic										
Fetal		P	P	P		P	P		P [2]	P [3]
Abdominal		P	P	P		P	P		P [2]	P [3]
Intraoperative (Abdominal)		N	N	N		N	N		N [2]	N [3]
Intraoperative Neurological										
Pediatric		P	P	P	P	P	P		P [2]	P [3]
Small Organ (specify) [1]		P	P	P	P	P	P		P [2]	P [3]
Neonatal Cephalic		P	P	P	P	P	P		P [2]	
Adult Cephalic		P	P	P	P	P	P		P [2]	
Cardiac		P	P	P	P	P			P [2]	P [3]
Transesophageal		P	P	P	P	P	P		P [2]	
Transrectal		P	P	P		P	P		P [2]	
Transvaginal		P	P	P		P	P		P [2]	
Transurethral										
Intravascular										
Peripheral Vascular		P	P	P	P	P	P		P [2]	
Laparoscopic										
Musculo-skeletal Conventional		P	P	P	P	P	P		P [2]	
Musculo-skeletal Superficial		P	P	P	P	P	P		P [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)

Compound Imaging

VPAN

Tissue Velocity Mapping (TVM)

CMM

CnTI

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Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)

Division of Reproductive, Abdominal, and Radiological Devices

510(k) Number K052805

Diagnostic Ultrasound Indications for Use Form

Model 7350

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		P	P	P		P	P		P [2]	P [3]
Abdominal		P	P	P		P	P		P [2]	P [3]
Intraoperative (Abdominal)		N	N	N		N	N		N [2]	N [3]
Intraoperative Neurological										
Pediatric		P	P	P	P	P	P		P [2]	P [3]
Small Organ (specify) [1]		P	P	P	P	P	P		P [2]	P [3]
Neonatal Cephalic		P	P	P	P	P	P		P [2]	
Adult Cephalic		P	P	P	P	P	P		P [2]	P [3]
Cardiac		P	P	P	P	P			P [2]	P [3]
Transesophageal		P	P	P	P	P			P [2]	
Transrectal		P	P	P		P	P		P [2]	
Transvaginal		P	P	P		P	P		P [2]	
Transurethral										
Intravascular										
Peripheral Vascular		P	P	P	P	P	P		P [2]	
Laparoscopic										
Musculo-skeletal Conventional		P	P	P	P	P	P		P [2]	
Musculo-skeletal Superficial		P	P	P	P	P	P		P [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 Harmonic Imaging (TEI)

CMM

Tissue Velocity Mapping (TVM)

VPAN

Compound Imaging

CnTI

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510(k) Number K052805

Diagnostic Ultrasound Indications for Use Form

Model 6150

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		P	P	P	P	P	P		P [2]	P [3]
Abdominal		P	P	P	P	P	P		P [2]	P [3]
Intraoperative (Abdominal)		N	N	N		N	N		N [2]	N [3]
Intraoperative Neurological										
Pediatric		P	P	P	P	P	P		P [2]	P [3]
Small Organ (specify) [1]		P	P	P	P	P	P		P [2]	P [3]
Neonatal Cephalic		P	P	P	P	P	P		P [2]	P [3]
Adult Cephalic		P	P	P	P	P	P		P [2]	P [3]
Cardiac		P	P	P	P	P	P		P [2]	P [3]
Transesophageal		P	P	P	P	P	P		P [2]	P [3]
Transrectal		P	P	P		P	P		P [2]	P [3]
Transvaginal		P	P	P		P	P		P [2]	P [3]
Transurethral										
Intravascular										
Peripheral Vascular		P	P	P	P	P	P		P [2]	P [3]
Laparoscopic										
Musculo-skeletal Conventional		P	P	P	P	P	P		P [2]	P [3]
Musculo-skeletal Superficial		P	P	P	P	P	P		P [2]	P [3]
Other (Urological)		P	P	P	P	P	P		P [2]	P [3]

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 Harmonic Imaging (TEI)

CMM
VPAN
Compound Imaging
CnTI
Tissue Velocity Mapping (TVM)

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510(k) Number K052805

7300, 7350, and 6150 Systems

IOE323

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

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

[1] Small organs include Thyroid, Breast and Testicles.
[2] Applicable combined modes: B+M+PW+CFM+PD
[3] TEI (Tissue Enhanced Imaging)
VPAN
Compound Imaging
CnTI

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510(k) Number K052805

7300 System

2 CW

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

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

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510(k) Number K052805

7300 System

5 CW

Clinical Application	Mode of Operation									
	A	B	M	PWD (PW)	CWD (CW)	Color Doppler (CFM)	Amplitude Doppler (PD)	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										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular					N					
Laparoscopic										
Muscolo-skeletal Conventional										
Muscolo-skeletal Superficial										
Other (Urological)										

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

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