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510(k) Summary

The following safety and effectiveness summary has been prepared pursuant to requirement for 510(k) summaries specified in 21CFR¶807.92(a).

807.92(a)(1)

Submitter Information

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Contact Person: Carri Graham

Date: December 15, 2004

807.92(a)(2)

Trade Name:	My Lab 15 / My Lab 20 Ultrasound Imaging Systems	
Common Name:	Ultrasound Imaging System	
Classification Name(s):	Ultrasonic pulsed echo imaging system Ultrasonic pulsed Doppler imaging system	892.1560 832.1550
Classification Number:	90IYO 90IYN	

807.92(a)(3)

Predicate Device(s)

Pie Medical	Picus	K023512
Medison	128BW	K012887

Additional Substantial Equivalence Information is provided in the following substantial Equivalence Comparison Table.

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807.92(a)(4) **Device Description**

The MyLab15/MyLab20 is a compact console ultrasound system intended to be used by a physician to perform general diagnostic ultrasound studies. Its primary modes of operation are: B-Mode, M-Mode, PW Doppler and Color Flow Mapping and Tissue Enhancement Imaging (TEI). The MyLab15/MyLab20 is equipped with either an LCD TFT color display or a CRT color monitor. The full alphanumeric keyboard allows complete on-screen data entry of patient information and on-screen annotations.
The MyLab15/MyLab20 can drive convex (CA) and linear array (LA) probes.
The MyLab15/MyLab20 permits storage of images on a USB memory stick. The MyLab15/MyLab20 also saves fetal biometry data, acquired during obstetric examinations, into a database in the internal memory of the system, in order to track the fetal growth through different examinations during the same gestation.
Optional accessories available for the MyLab15/MyLab20 include an S-VHS video recorder and a monochrome or color printer.

807.92(a)(5) **Intended Use(s)**

Esaote's MyLab15/MyLab20 is a compact console ultrasound system intended to be used by a physician to perform general diagnostic ultrasound studies including Fetal, Abdominal, Pediatric, Small organ, Neonatal Cephalic, Cardiac, Transrectal, Transvaginal, Peripheral Vascular, Musculoskeletal (Conventional and Superficial).

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Comparison Chart for Substantial Equivalence

General Characteristics	Esaote MyLab15/MyLab20	Esaote Picus (K023512)	Medison 128BW (K012887)
Applications			
Fetal	**Yes**	**Yes**	**Yes**
Abdominal	**Yes**	**Yes**	**Yes**
Pediatric	**Yes**	**No**	**Yes**
Small Organ	**Yes**	**Yes**	**Yes**
Neonatal Cephalic	**Yes**	**Yes**	**Yes**
Adult Cephalic	**No**	**No**	**Yes**
Cardiac	**Yes**	**Yes**	**Yes**
Transrectal	**Yes**	**Yes**	**Yes**
Transvaginal	**Yes**	**Yes**	**Yes**
Peripheral Vascular	**Yes**	**Yes**	**Yes**
Musculo-skeletal (Conventional and superficial)	**Yes**	**No**	**Yes**

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General Characteristics	Esaote MyLab15/MyLab20	Esaote Picus (K023512)	Medison 128BW (K012887)
Transducer Type			
Linear	**Yes**	**Yes**	**Yes**
Convex	**Yes**	**Yes**	**Yes**
2D Freq MHz	**2.7 – 12.5**	**2.5 - 10**	**2.0 – 10**
PW Freq MHz	**2.7 – 6.3**	**2.5 – 8**	**No**
Multifrequency probes	**Yes**	**Yes**	**Yes**
Special probes	Endocavity probe	Endocavity probe	Endocavity probe
Biopsy attachments			
Convex	**Yes**	**Yes**	**Yes**
Linear	**Yes**	**Yes**	**Yes**
Imaging modes			
Real Time 2D	**Yes**	**Yes**	**Yes**
M-mode	**Yes**	**Yes**	**Yes**
PW Doppler	**Yes**	**Yes**	**No**
CFM Doppler	**Yes**	**Yes**	**No**
Amplitude Doppler	**Yes**	**Yes**	**No**
Triplex	**Yes**	**Yes**	-
Monitor size (inches)	**15" CRT monitor** **15" LCD**	**15" CRT monitor** 10" LCD	**12" CRT monitor**
ECG	**Optional**	**Optional**	**No**
Digital archival capabilities	**Yes**	**Yes**	**Yes**
VCR & Video printers	**Yes**	**Yes**	**Yes**
M&A capabilities	**Cardiac, vascular, Obstetric, Gynaecologic, Urology, and general purpose measurements**	**Cardiac, vascular, Obstetric, Gynaecologic, Urology, and general purpose measurements**	**OB/Gyn and general purpose measurements**
Safety			
Electrical safety	**EN60601-1**	**EN60601-1**	**EN60601-1**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 25 2005

Pie Medical
% Ms. Carri Graham
Consultant
The Anson Group
7992 Castleway Drive
INDIANAPOLIS IN 46250

Re: K043588
Trade Name: MyLab15 / MyLab20
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Number: 21 CFR 892.1560
Regulatory Name: Ultrasonic pulsed echo imaging system
Regulatory Number: 21 CFR 892.1570
Regulatory Name: Diagnostic ultrasonic transducer
Regulatory Class: II
Product Code: 90 IYN, IYO, and ITX
Dated: December 21, 2004
Received: December 28, 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 MyLab15 / MyLab20, as described in your premarket notification:

Transducer Model Number

LA523	EC123
CA421P	E8-5 R10

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/dsma/dsmamain.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)

4.3 Indications for Use

The following table provides the intended clinical use for the MyLab15/MyLab20:

	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 [2]	N
Small Organ (specify) [1]		N	N	N		N	N		N [2]	N
Neonatal Cephalic		N	N	N		N	N		N [2]	N
Adult Cephalic										
Cardiac		N	N	N		N	N		N [2]	N
Transesophageal										
Transrectal		N	N	N		N	N		N [2]	N
Transvaginal		N	N	N		N	N		N [2]	N
Transurethral										
Intravascular										
Peripheral Vascular		N	N	N		N	N		N [2]	N
Laparoscopic										
Musculo-skeletal Conventional		N	N	N		N	N		N [2]	N
Musculo-skeletal Superficial		N	N	N		N	N		N [2]	N
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+ CFM+Amplitude Doppler

[3] Tissue Enhancement Imaging (TEI)

Prescription Use ✓

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Division of Reproductive, Abdominal,
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510(k) Number K043588

The following tables provide the intended clinical use for the MyLab15/MyLab20 probes in combination with the system:

Transducer: **LA523**

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

[3] Tissue Enhancement Imaging (TEI)

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Transducer: **CA421P**

Clinical Application	Mode of Operation									
	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+Amplitude Doppler.

[2] Tissue Enhancement Imaging (TEI)

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Transducer: **EC123**

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify) TEI [2]
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]	N
Transvaginal		N	N	N		N	N		N[1]	N
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+Amplitude Doppler.

[2] Tissue Enhancement Imaging (TEI)

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Transducer: **E8-5 R10**

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify) TEI [2]
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]	N
Transvaginal		N	N	N		N	N		N[1]	N
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+Amplitude Doppler.

[2] Tissue Enhancement Imaging (TEI)

Prescription Use ✓

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510(k) Number K043588