

4/30/99

510(k) Summary
AU6
Biosound Esaote

K99D360

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

Colleen Hittle, Official Correspondent
8000 Castleway Drive
Indianapolis, IN 46250
Phone: (317) 849-1916
Facsimile: (317) 577-9070

Contact Person: Colleen Hittle

Date: February 3, 1999

807.92(a)(2)

Trade Name: AU6
Common Name: Ultrasound Imaging System
Classification Name(s): System, Imaging, Pulsed Doppler, Ultrasonic
Classification Number: 90IYN; 90IYO

807.92(a)(3)

Predicate Device(s)

Esaote AU5 K980468

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

510(k) Summary
AU6
Biosound Esaote

807.92(a)(5)

Intended Use(s)

The AU6 ultrasound imaging system is intended to be used by a physician for diagnostic imaging in cardiac, abdominal, peripheral vessel and fetal applications.

Comparison Chart for Substantial Equivalence

General Characteristics	Esaote	Esaote
	AU5 (K#980468)	AU6 Digital
Transducer Type	Annular Array	Annular Array
	Mechanical Sector	Mechanical Sector
	Linear	Linear
	Convex	Convex
	Phased Array	Phased Array
	NO	1.5D
2D Freq MHz	2.5/15	2.5/15
PW Freq MHz	2.25/10	2.25/15
CW Freq MHz	2.25/5.0	2.25/10
1.5 D	NO	3.5/10
Imaging Modes	Real-time/2D	Real-time/2D
	M Mode	M Mode
	PW Doppler	PW Doppler
	CW Doppler	CW Doppler
	CFM Doppler	CFM Doppler
	Power Doppler	Power Doppler
	Triplex	Triplex
Probes MHz		
Annular Array	10-20	20
Linear	5.0-13	5.0-10.0
Convex	3.5-7.5	3.5-5.0
Phased Array	2.5-3.5	2.5-10
1.5 D	NO	3.5-10
Multifrequency probes	Yes	Yes
Special probes	IVT transvaginal	IVT transvaginal
	TRT transrectal	TRT transrectal
		TEE transesophageal
	LP laparoscopic	LP laparoscopic
	IOE intraoperative	IOE intraoperative
Biopsy attachments	Convex	Convex
	Linear	Linear
Monitor size (inches)	14	15
Programmability	6 presets	10 presets
Pulsed/CW Doppler	Yes	Yes
HIPRF	No	Yes
2D Updating	Yes	Yes
CW steerable	Yes	Yes
Audio stereo	Yes	Yes
Color Doppler upgrade	Yes	Yes
ECG	Option	Option
Interconnectivity	NO	YES
DSM integrated	YES	YES
Computer interface	Centronics output	Centronics output
External Size-width	540 mm	580 mm
-height	540 mm	1440 mm
-depth	690 mm	1100 mm



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 30 1999

Colleen J. Hittle
The Anson Group
7992 Castleway Drive
Indianapolis, Indiana 46250

Re: K990360
AU6 Diagnostic Ultrasound System
Dated: April 9, 1999
Received: April 9, 1999
Regulatory Class: II
21 CFR 892.1550/Procode: 90 IYN

Dear Ms. Hittle:

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 AU6 Diagnostic Ultrasound System as described in your premarket notification:

Transducer Model Number

CA11	IOE13A
LA13A	LP13A
IVT22	TRT12
SMA50	PA11B
TEE 22	PT10A

P10A

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.

Page -2 – Ms. Hittle:

Please be advised that the determination above is based on the fact that no medical devices have been demonstrated to be safe and effective for in vitro fertilization or percutaneous umbilical blood sampling, nor have any devices been marketed for these uses in interstate commerce prior to May 28, 1976, or reclassified into class I (General Controls) or class II (Special Controls). FDA considers devices specifically intended for in vitro fertilization and percutaneous umbilical blood sampling to be investigational, and subject to the provision of the investigational device exemptions (IDE) regulations, 21 CFR, Part 812. Therefore, your product labeling must be consistent with FDA's position on this use.

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

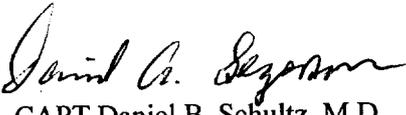
This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

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>".

Page -3 - Ms. Hittle

If you have any questions regarding the content of this letter, please contact Rodrigo Perez at (301) 594-1212.

Sincerely yours,

for 

CAPT Daniel B. Schultz, M.D.
Acting Director
Division of Reproductive,
Abdominal, Ear, Nose and Throat
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

AU6 System

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

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

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

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

Additional Comments: Small organs (specifically, thyroid, testicles and breast); Peripheral Vascular to include Vein Mapping & Sclerotherapy
 Applicable combined modes: B+PW+CFM+M+PD

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

1990 360

Congurrence of CDRH, Office of Device Evaluation (ODE)
 Prescription Use

Shirley A. Syman (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

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

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

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

Additional Comments: Applicable combined modes: B+PW+CFM+M+PD

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Concurrence of CDRH, Office of Device Evaluation (ODE)

K990360

David A. Johnson Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

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

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler CFM	Amplitude Doppler PD	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify) Abdominal		P	P	P		P	P		See comments	
Intraoperative (specify) Peripheral vascular		E	E	E		E	E		See comments	
Intraoperative Neurological										
Pediatric										
Small Organ (specify)		E	E	E		E	E		See comments	
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Tranesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		P	P	P		P	P		See comments	
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other										

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

Additional Comments: Small organs (specifically, thyroid, testicles and breast; Peripheral vascular to include Vein Mapping & Sclerotherapy

Applicable combined modes: B+PW+CFM+M+PD

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

Prescription Use Concurrence of CDRH, Office of Device Evaluation (ODE) K990360
 (Per 21 CFR 801.109)

David A. Segerson

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

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

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

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

Additional Comments: Small Organs (specifically, thyroid, testicles, and breast); Peripheral Vascular to include Vein Mapping & Sclerotherapy

Applicable combined modes: B+PW+CFM+M+PD

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Concurrence of CDRH, Office of Device Evaluation (ODE)

K990360

Prescription Use
(Per 21 CFR 801.109)

David G. Beggs

LP13A

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

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

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	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										
Laparoscopic		P	P	P		P	P		See comments	
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other										

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

Additional Comments: Applicable combined modes: B+PW+CFM+M+PD

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Concurrence of CDRH, Office of Device Evaluation (ODE) *K990360*

Prescription Use
(Per 21 CFR 801.109)

David A. Seymour

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

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

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	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										
Tranosophageal										
Transrectal		N	N	N		N	N		See comments	
Transvaginal		N	N	N		N	N		See comments	
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other-Urological		N	N	N		N	N		See comments	

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

Additional Comments: Applicable combined modes: B+PW+CFM+M+PD

(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)

K990360
David A. Seymour

TRT12

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

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

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	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		E	E	E		E	E		See comments	
Transvaginal		P	P	P		P	P		See comments	
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other-Urological		N	N	N		N	N		See comments	

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

Additional Comments: Applicable combined modes: B+PW+CFM+M+PD

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

Concurrence of CDRH, Office of Device Evaluation (ODE) *K990360*

Prescription Use
 (Per 21 CFR 801.109)

David A. Seymour

SMA50

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

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

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

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Additional Comments: Small Organs (specifically, thyroid, testicles, and breast); Peripheral vascular to include Vein Mapping & Sclerotherapy

Applicable combined modes: B + M

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Concurrence of CDRH, Office of Device Evaluation (ODE) *K990300*

Prescription Use
(Per 21 CFR 801.109)

David G. Szeman 19

PA11B

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

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

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

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

Additional Comments: : Applicable combined modes: B+PW+CW+CFM+M+PD

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

K990360

Prescription Use
(21 CFR 801.109)

David L. Ferguson

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

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Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal		N	N	N	N	N	N		See Comments	
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
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Musculo-skeletal Superficial										
Other										

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

Additional Comments: Applicable combined modes: B+PW+CFM+M+PD+CW

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

K990360

Prescription Use
(Per 21 CFR 801.109)

David A. Seymour

PT10A

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

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

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	A	B	M	PWD	CWD	Color Doppler CFM	Amplitude Doppler PD	Color Velocity Imaging	Combined (specify)	Other (specify)
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Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic				P						
Cardiac										
Tranesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular				E						
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other										

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

Additional Comments: _____

(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)

K990360
David L. Beynon

P10A

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

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

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	A	B	M	PWD	CWD	Color Doppler CFM	Amplitude Doppler PD	Color Velocity Imaging	Combined (specify)	Other (specify)
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Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac					P					
Tranesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular					E					
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other										

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Additional Comments: _____

(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. Heger

K990360