JUN 30 1998

Safety and Effectiveness Summary
7200 Ultrasound Imaging System
Biosound Esaote

Safety and Effectiveness 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
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Indianapolis, IN 46250
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Contact Person: Colleen Hittle

Date: March 13, 1998

807.92(a)(2)

Trade Name:	7200 Ultrasound Imaging System	
Common Name:	Ultrasound Imaging System	
Classification Name(s):	Ultrasonic pulsed doppler imaging system Ultrasonic pulsed echo imaging system	892.1550 892.1560
Classification Number:	90IYN 90IYO	

807.92(a)(3)

Predicate Device(s)

Esaote	7050 (AU3)	K944287

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

Safety and Effectiveness Summary
7200 Ultrasound Imaging System
Biosound Esaote

Comparison Chart for Substantial Equivalence

	7200	7050
Electrical Safety	EN60601-1	EN60601-1
Ultrasound Safety	Track 3 (Acoustic Output Display)	Track 3 (Acoustic Output Display)
Intended Use		
• Cardiac (Transthoracic)	YES	YES
• Cardiac (Transesophageal)	YES	YES
• Vascular	YES	YES
• Abdominal	YES	YES
• Fetal	YES	YES
• Adult Transcranial	YES	YES
• Neonatal Head/Small parts	YES	YES
• Endovaginal	NO	YES
• Endorectal	NO	YES
Biopsy Guidance	NO	YES
Probe Technology		
• Annular Array	YES	YES
• Electronical Array	NO	YES
• Doppler Probes	YES	YES
Modes of operation	2D, M-Mode, PW, CW, CFM	2D, M-Mode, PW, CW, CFM
Imaging Frequencies	2.5, 3.5, 5.0, 7.5, 10 MHz	2.5, 3.5, 5.0, 7.5, 10 MHz
CFM/Doppler Frequencies	2.0, 2.5, 3.3, 5.0, 6.6 MHz	2.0, 2.5, 3.3, 5.0, 6.6 MHz
Display Type	SVGA	RGB
Digital Archival Capabilities	YES	YES
VCR / Page Printer	YES	YES
M&A Capabilities	Cardiac, Vascular, OB and general purpose measurements	Cardiac, Vascular, OB and general purpose measurements

Safety and Effectiveness Summary
7200 Ultrasound Imaging System
Biosound Esaote

807.92(a)(4)

Device Description

ESAOTE's Mod.7200 is a compact ultrasound system used to perform non-invasive diagnostic general ultrasound studies. Its primary modes of operation are the following: B-Mode, M-Mode, Doppler and Color Flow Mapping. The MOD.7200 can be equipped with an LCD Color Display (Portable Configuration) or with a 15" Color Monitor and a cart (Mainframe Configuration). The full alphanumeric keyboard allows complete on-screen data entry of patient information and on-screen annotations.
The MOD.7200 uses annular phased array probes; its design provides a dynamically focused ultrasound beam. The MOD.7200 offers a vast selection of calculations and measurements which can be performed quickly and easily.
The MOD.7200 is designed for ease of use. The user interface allows the operator to perform an examination quickly and efficiently. Clearly labeled mode selection keys are easily accessed, and the system's "pop-up" menus allow the operator to change parameters with ease. The user may also access special function menus and perform calculations with a minimal number of key strokes.
The MOD.7200 is equipped with a 3.5" floppy disk drive to simplify software modifications and provides fast, cost effective system upgrades. This drive can also be used for image storage.
In addition, this system can be equipped with recording devices, including a S-VHS video recorder and a black-and-white or color page printer, which are controlled through the keyboard.

807.92(a)(5)

Intended Use(s)

The 7200 Ultrasound Imaging System is a compact ultrasound system used to perform non-invasive diagnostic general ultrasound studies.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 30 1998

Collen Hittle
Official Correpondent
Biosound Esaote, Inc.
8000 Castleway Dr.
Indianapolis, IN 46250

Re: K981293
7200 Ultrasound Imaging System
Dated: April 7, 1998
Received: April 9, 1998
Regulatory class: II
21 CFR 892.1550/Procode: 90 IYN
21 CFR 892.1560/Procode: 90 IYO
21 CFR 892.1570/Procode: 90 ITX

Dear Ms. Collen:

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 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. You may, therefore, market the device, subject to the general controls provisions Act (Act). The general controls provisions of the Act include requirements for registration, listing of devices, good manufacturing practices, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the 7200 Ultrasound Imaging System, as described in your premarket notification:

Transducer Model Number

2535 AA-C
3550 AA-C
7510 AA-C
5 MHz TEE

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.

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".

If you have any questions regarding the content of this letter, please contact Paul Gammell, Ph.D. at (301) 594-1212.

Sincerely yours,

for David A. Lyon

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

K981293

Diagnostic Ultrasound Indications for Use Form

Mod.7200

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

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concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K981293

K981293

Diagnostic Ultrasound Indications for Use Form

Transducer: 2535 AA-C

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		P	P	P	P	P				
Cardiac		P	P	P	P	P				
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: This transducer has been previously cleared by FDA with the AU3 unit (K944287).

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concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Flynn

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

Prescription Use (Per 21 CFR 801.109)

510(k) Number K981293

K981293

Diagnostic Ultrasound Indications for Use Form

Transducer: **3550 AA-C**

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		N	N	N	N	N				
Abdominal		N	N	N	N	N				
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		P	P	P	P	P				
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac		P	P	P	P	P				
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: This transducer has been previously cleared by FDA with the AU3 unit (K944287) for uses indicated as "P".

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concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

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

510(k) Number K981293

Diagnostic Ultrasound Indications for Use Form

Transducer: **7510 AA-C**

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		P	P	P	P	P				
Small Organ (specify) [1]		P	P	P	P	P				
Neonatal Cephalic		P	P	P	P	P				
Adult Cephalic										
Cardiac		P	P	P	P	P				
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		P	P	P	P	P				
Laparoscopic										
Musculo-skeletal										
Conventional										
Musculoskeletal Superficial										
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. This transducer has been previously cleared by FDA with the AU3 unit (K944287).

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concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A. Hyman

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K981293

K981293

Diagnostic Ultrasound Indications for Use Form

Transducer: **5 MHz TEE**

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		P	P	P	P	P				
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: This transducer has been previously cleared by the FDA for use with the GenesisCFM and for use with the AU3 (K913209 and K953579)

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concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K981293