FEB 2 4 2000

K994369

510(k)
7250 Ultrasound Imaging System
Biosound Esaote

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
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Indianapolis, IN 46250
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Contact Person: Colleen Hittle

Date: December 23, 1999

807.92(a)(2)

Trade Name:	7250 Ultrasound Imaging System (Megas) (Addition of 2nd Harmonic Imaging Mode)	
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	7250 (Megas)	K982444

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

510(k)
7250 Ultrasound Imaging System
Biosound Esaote

Device Description

ESAOTE's 7250 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, Color Flow Mapping, Harmonic Imaging (TEI) and Amplitude Doppler. The 7250 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 7250 can drive annular array, phased, convex and linear array probes. In addition, the 7250 is equipped with a volumetric scan converter and the ability to control simultaneously two independent scan planes. This technological characteristic allows to manage Bi-Scan Probes, to obtain volumetric datasets; these datasets can then be used to display "omni-directional" 2D images (anyplane sectioning) as well as multiple parallel equidistant sections (paraplane sectioning). This Bi-Scan approach is ideal for volume computations through the Simpson rule; specifically, it can be used to measure volumes of irregular structures since it does not require a geometrical assumption.

The 7250 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 7250 offers a vast selection of calculations and measurements which can be performed quickly and easily.

The MOD.7250 is equipped with a 3.5" floppy disk drive to simplify software modifications and provide fast, cost effective system upgrades. This drive (or an optional Optical Disk Drive) can also be used for image storage. Moreover, this unit can store data directly to a Personal Computer via a LAN (Network) port.

In addition, the 7250 can be equipped with recording devices, including a S-VHS video recorder and a black-and-white or color printer, which are controlled through the keyboard.

807.92(a)(5)

Intended Use(s)

ESAOTE's Mod. 7250 is a compact ultrasound system used to perform non-invasive diagnostic general ultrasound studies.

510(k) Summary
7250 Ultrasound Imaging System
Biosound Esaote

Comparison Chart for Substantial Equivalence

	7250 (predicate)	**7250 (new mode)**
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 (Multiplane)	YES (Multiplane)
• Vascular	YES	YES
• Abdominal	YES	YES
• Fetal	YES	YES
• Adult Cephalic	YES	YES
• Neonatal Cephalic/Small organ	YES	YES
• Endovaginal	YES (Sagittal & Transverse Planes)	YES (Sagittal & Transverse Planes)
• Endorectal	YES (Sagittal & Transverse Planes	YES (Sagittal & Transverse Planes
Probe Technology		
• Annual Array	YES	YES
• Electronical Array	YES	YES
• Bi-Scan Probes	YES	YES
• Doppler Probes	YES	YES
Modes of operation	2D, M-Mode, PW, CW, CFM, Amplitude Doppler	2D, M-Mode, PW, CW, TEI, CFM, Amplitude Doppler
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
Biopsy Guidance	YES	YES
• ABS11 & ABS13 use	General Purpose	General Purpose
• ABS12 use	Transrectal/transvaginal	Transrectal/transvaginal
• Biopsy Line Depth marker	1 cm	1 cm
• Needle guide angle	ABS11: 25-45°	ABS11: 25-45°
	ABS12: fixed	ABS12: fixed
	ABS13: 30-50°	ABS13: 30-50°
Display Type	SVGA	SVGA
Digital Archival Capabilities	YES	YES
VCR/Page Printer	YES	YES
M&A Capabilities	Cardiac, Vascular, Fetal and general purpose measurements	Cardiac, Vascular, Fetal and general purpose measurements

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 24 2000

Colleen J. Hittle
Official Correspondent
Biosound Esaote, Inc.
8000 Castleway Drive
Indianapolis, IN 46250

Re: K994369
7250 Ultrasound Imaging System (Addition of Tissue Enhancement Imaging)
Regulatory class: II/21 CFR 892.1550 and 21 CFR 892.1560
Product Code: 90 IYN/90 IYO
Dated: December 23, 1999
Received: December 27, 1999

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 7250 Ultrasound Imaging System, as described in your premarket notification:

Transducer Model Number

PA220E

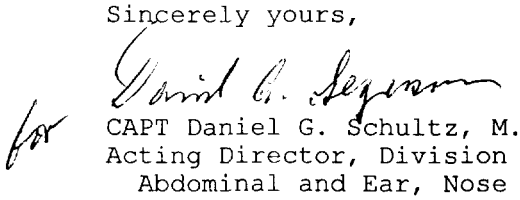
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

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

Sincerely yours,



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

Enclosure

Diagnostic Ultrasound Indications for Use Form

Mod.7250

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		See comments	
Abdominal		P	P	P		P	P		See comments	
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		P	P	P	P	P	P		See Comments	
Small Organ (specify) [1]		P	P	P	P	P	P		See Comments	
Neonatal Cephalic		P	P	P	P	P	P		See Comments	
Adult Cephalic		P	P	P	P	P	P		See Comments	
Cardiac		P	P	P	P	P			See Comments	N[2]
Transesophageal		P	P	P	P	P			See Comments	
Transrectal		P	P	P		P	P		See Comments	
Transvaginal		P	P	P		P	P		See Comments	
Transurethral										
Intravascular										
Peripheral Vascular		P	P	P	P	P	P		See Comments	P[3]
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. [2] Tissue Harmonic Imaging. [3] This unit manages Bi-scan probes for volumetric acquisitions from which any 2D tomographic image can be displayed. This unit has been previously cleared by FDA (K982444) for uses indicated as "P".
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. Seppman

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K994369

Diagnostic Ultrasound Indications for Use Form

Transducer: **PA220E**

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) [1]										
Neonatal Cephalic										
Adult Cephalic		P	P	P	P	P	P		See Comments	
Cardiac		P	P	P	P	P			See Comments	N[2]
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: [2] Tissue Harmonic Imaging. This probe has been previously cleared by FDA (K982444) for uses indicated as "P". Applicable combined modes: B+M+PW+CW+CFM+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)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K994369