

AUG 26 1998

K980468

Safety and Effectiveness Summary
AU5
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
8000 Castleway Drive
Indianapolis, IN 46250
Phone: (317) 849-1916
Facsimile: (317) 577-9070

Contact Person: Colleen Hittle

Date: January 27, 1998
Revised: June 1, 1998

807.92(a)(2)

Trade Name: AU5
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 AU4 K944485

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

Safety and Effectiveness Summary
AU5
Biosound Esaote

807.92(a)(5)

Intended Use(s)

The AU5 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 AU5 | Esaote AU4 (K#944485) |
|--------------------------------|-----------------------|----------------------------------|
| <u>Transducer Type</u> | Annular Array | Annular Array |
| | Mechanical Sector | Mechanical Sector |
| | Linear | Linear |
| | Convex | Convex |
| | Phased Array | Phased Array |
| 2D Freq MHz | 2.5/15 | 2.5/15 |
| PW Freq MHz | 2.25/10 | 2.25/10 |
| CW Freq MHz | 2.25/5.0 | 2.25/5.0 |
| <u>Imaging Modes</u> | 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 |
| <u>Probes MHz</u> | | |
| Annular array | 2.5, 3.5, 7.5, 10, 13 | 2.5, 3.5, 7.5, 10, 13 |
| Mechanical Sector | 13 | 13 |
| Linear | 3.5 – 7.5 | 3.5 - 7.5 |
| Convex | 3.5 – 5.0 | 3.5 - 5.0 |
| Multifrequency probes | Yes | Yes |
| <u>Special probes</u> | IVT transvaginal | IVT transvaginal |
| | TRT transrectal | TRT transrectal |
| <u>Biopsy attachments</u> | Linear Array | Linear Array |
| | Convex | Convex |
| Monitor size (inches) | 14 | 12 |
| Programmability | 6 presets | 6 presets |
| Pulsed/CW Doppler | Yes | Yes |
| HIPRF | No | No |
| 2D Updating | Yes | Yes |
| CW steerable | Yes | Yes |
| Audio stereo | Yes | Yes |
| Color doppler upgrade | Yes | Yes |
| ECG | Option | Option |
| Computer interface | centronics output | centronics output |
| DSM (Dicom storage module) | Yes | No |
| External size - width | 540 mm | 540 mm |



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850Colleen Hittle
Official Correspondent
Biosound Esaote
8000 Castleway Drive
Indianapolis, IN 46350Re: K980468
AU5 Ultrasound Imaging System
Regulatory Class: II/21 CFR 892.1550
Product Code: 90 IYN
Dated: July 27, 1998
Received: July 28, 1998

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 AU5 Ultrasound Imaging System, as described in your premarket notification:

Transducer Model Number

CA11, CA13, CA711A, IOE13A, IVT12,
LA12, LA13A, LA14, TRT12, LP13A, P10A,
P12A, PT10A, PA11A, SMA50, SMA32

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

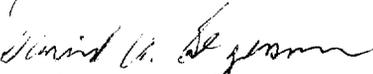
This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

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>".

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

Sincerely yours,

for 

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