

K982444

P 1 of 3

OCT 6 1998

Safety and Effectiveness Summary  
7250 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  
8000 Castleway Drive  
Indianapolis, IN 46250  
Phone: (317) 849-1916  
Facsimile: (317) 577-9070

Contact Person: Colleen Hittle

Date: July 2, 1998

### 807.92(a)(2)

Trade Name: 7250 Ultrasound Imaging System

Common Name: Ultrasound Imaging System

Classification Name(s): Ultrasonic pulsed doppler imaging system 892.1550  
Ultrasonic pulsed echo imaging system 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  
7250 Ultrasound Imaging System  
Biosound Esaote

807.92(a)(4)

### **Device Description**

ESAOTE's Mod.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 and Amplitude Doppler. The MOD.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 MOD.7250 can drive annular array, phased, convex and linear array probes. In addition, Mod.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 MOD.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 MOD.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 provides 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, MOD.7250 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)**

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

Safety and Effectiveness Summary  
7250 Ultrasound Imaging System  
Biosound Esaote

**Comparison Chart for Substantial Equivalence**

|                                 | <b>7250</b>   | <b>7050</b>   |
|---------------------------------|---|---|
| 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 (Monoplane)   |
| • 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   | NO  |
| • Doppler Probes                | YES   | YES   |
| Modes of operation              | 2D, M-Mode, PW, CW, CFM, Amplitude Doppler                | 2D, M-Mode, PW, CW, 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  | RGB   |
| 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 |



OCT 6 1998

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850Colleen Hittle  
Official Correspondent  
Biosound Esaote  
8000 Castleway Drive  
Indianapolis, IN 46250Re: K982444  
7250 Ultrasound Imaging System  
Regulatory Class: II  
Product Code: 90 IYO/21 CFR 892.1560  
Dated: July 2, 1998  
Received: July 14, 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 Mod. 7250, as described in your premarket notification:

Transducer Model Number

PA020  
CA11  
7510 AA-C  
LA13  
BLA023  
5 MHz TEE  
TRT12

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>".

Page 3 - Colleen Hittle

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. Seymour*

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

K 982444

Diagnostic Ultrasound Indications for Use Form

Mod.7250

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<br>CFM | Amplitude Doppler<br>PD | Color Velocity Imaging | Combined (specify) | Other (specify) |
| Ophthalmic                  |                   |   |   |     |     |                      |                         |                        |                    |                 |
| Fetal                       |                   | N | N | N   |     | N                    | N                       |                        | See comments       |                 |
| Abdominal                   |                   | N | N | N   |     | N                    | N                       |                        | See comments       |                 |
| Intraoperative (specify)    |                   |   |   |     |     |                      |                         |                        |                    |                 |
| Intraoperative Neurological |                   |   |   |     |     |                      |                         |                        |                    |                 |
| Pediatric                   |                   | N | N | N   | N   | N                    | N                       |                        | See comments       |                 |
| Small Organ (specify) [1]   |                   | 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                       |                        | See comments       |                 |
| Cardiac                     |                   | N | N | N   | N   | N                    |                         |                        | See comments       |                 |
| Transesophageal             |                   | N | N | N   | N   | N                    |                         |                        | See comments       |                 |
| Transrectal                 |                   | N | N | N   |     | N                    | N                       |                        | See comments       |                 |
| Transvaginal                |                   | N | N | N   |     | N                    | N                       |                        | See comments       |                 |
| Transurethral               |                   |   |   |     |     |                      |                         |                        |                    |                 |
| Intravascular               |                   |   |   |     |     |                      |                         |                        |                    |                 |
| Peripheral Vascular         |                   | N | N | N   | N   | N                    | N                       |                        | See comments       | N[2]            |
| 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] This unit manages Bi-scan probes for volumetric acquisitions from which any 2D tomographic image can be displayed.

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

*David A. Segerson*  
 (Division Sign-Off)

(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED)  
 concurrence of CDRH, Office of Device Evaluation (ODE) Division of Reproductive, Abdominal, ENT, and Radiological Devices

Prescription Use (Per 21 CFR 801.109)

510(k) Number K982444

K 982444

Diagnostic Ultrasound Indications for Use Form

Transducer: PA020

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<br>CFM | Amplitude Doppler<br>PD | Color Velocity Imaging | Combined (specify) | Other (specify) |
| Ophthalmic                  |                   |   |   |     |     |                      |                         |                        |                    |                 |
| Fetal                       |                   |   |   |     |     |                      |                         |                        |                    |                 |
| Abdominal                   |                   |   |   |     |     |                      |                         |                        |                    |                 |
| 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                    |                         |                        | See comments       |                 |
| 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: / Applicable combined modes: B+M+PW+CW+CFM+PD

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

concurrency of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

*David A. Johnson*  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal, ENT,  
 and Radiological Devices  
 510(k) Number K982444

Diagnostic Ultrasound Indications for Use Form

Transducer: CA11

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<br>CFM | Amplitude Doppler<br>PD | 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                   |                   |   |   |     |     |                      |                         |                        |                    |                 |
| Small Organ (specify)       |                   |   |   |     |     |                      |                         |                        |                    |                 |
| Neonatal Cephalic           |                   |   |   |     |     |                      |                         |                        |                    |                 |
| Adult Cephalic              |                   |   |   |     |     |                      |                         |                        |                    |                 |
| Cardiac                     |                   |   |   |     |     |                      |                         |                        |                    |                 |
| 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". Applicable combined modes: B+M+PW+CFM+PD

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

concurrency of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A. Johnson  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal, ENT,  
 and Radiological Devices  
 510(k) Number K982444

K982444

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:

| Clinical Application        | Mode of Operation |   |   |     |     |                      |                         |                        |                    |                 |
|-----------------------------|-------------------|---|---|-----|-----|----------------------|-------------------------|------------------------|--------------------|-----------------|
|                             | A                 | B | M | PWD | CWD | Color Doppler<br>CFM | Amplitude Doppler<br>PD | Color Velocity Imaging | Combined (specify) | Other (specify) |
| Ophthalmic                  |                   |   |   |     |     |                      |                         |                        |                    |                 |
| Fetal                       |                   |   |   |     |     |                      |                         |                        |                    |                 |
| Abdominal                   |                   |   |   |     |     |                      |                         |                        |                    |                 |
| Intraoperative (specify)    |                   |   |   |     |     |                      |                         |                        |                    |                 |
| Intraoperative Neurological |                   |   |   |     |     |                      |                         |                        |                    |                 |
| Pediatric                   |                   | N | N | N   | N   | N                    |                         |                        | See comments       |                 |
| Small Organ (specify) [1]   |                   | P | P | P   | P   | P                    |                         |                        | See comments       |                 |
| Neonatal Cephalic           |                   | P | P | P   | P   | P                    |                         |                        | See comments       |                 |
| Adult Cephalic              |                   |   |   |     |     |                      |                         |                        |                    |                 |
| Cardiac                     |                   | N | N | N   | N   | N                    |                         |                        | See comments       |                 |
| Transesophageal             |                   |   |   |     |     |                      |                         |                        |                    |                 |
| Transrectal                 |                   |   |   |     |     |                      |                         |                        |                    |                 |
| Transvaginal                |                   |   |   |     |     |                      |                         |                        |                    |                 |
| Transurethral               |                   |   |   |     |     |                      |                         |                        |                    |                 |
| Intravascular               |                   |   |   |     |     |                      |                         |                        |                    |                 |
| Peripheral Vascular         |                   | P | P | P   | P   | P                    |                         |                        | See comments       |                 |
| 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). Applicable combined modes: B+M+PW+CW+CFM

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

concurrence of CDRH, Office of Device Evaluation (ODE)

*David A. Egan*  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal, ENT,  
 and Radiological Devices  
 510(k) Number K982444

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

Transducer: LA13

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<br>CFM | Amplitude Doppler<br>PD | Color Velocity Imaging | Combined (specify) | Other (specify) |
| Ophthalmic                  |                   |   |   |     |     |                      |                         |                        |                    |                 |
| Fetal                       |                   |   |   |     |     |                      |                         |                        |                    |                 |
| Abdominal                   |                   |   |   |     |     |                      |                         |                        |                    |                 |
| Intraoperative (specify)    |                   |   |   |     |     |                      |                         |                        |                    |                 |
| Intraoperative Neurological |                   |   |   |     |     |                      |                         |                        |                    |                 |
| Pediatric                   |                   |   |   |     |     |                      |                         |                        |                    |                 |
| Small Organ (specify) [1]   |                   | N | N | N   |     | N                    | N                       |                        | See comments       |                 |
| Neonatal Cephalic           |                   |   |   |     |     |                      |                         |                        |                    |                 |
| Adult Cephalic              |                   |   |   |     |     |                      |                         |                        |                    |                 |
| Cardiac                     |                   |   |   |     |     |                      |                         |                        |                    |                 |
| Transesophageal             |                   |   |   |     |     |                      |                         |                        |                    |                 |
| Transrectal                 |                   |   |   |     |     |                      |                         |                        |                    |                 |
| Transvaginal                |                   |   |   |     |     |                      |                         |                        |                    |                 |
| Transurethral               |                   |   |   |     |     |                      |                         |                        |                    |                 |
| Intravascular               |                   |   |   |     |     |                      |                         |                        |                    |                 |
| Peripheral Vascular         |                   | P | P | P   | P   | P                    | P                       |                        | See comments       |                 |
| 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). Applicable combined modes: B+M+PW+CFM+PD

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

concurrency of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

*David A. Soyson*  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal, ENT,  
 and Radiological Devices  
 510(k) Number K982444

Diagnostic Ultrasound Indications for Use Form

Transducer: BLA023

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<br>CFM | Amplitude Doppler<br>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         |                   | N | N | N   |     | N                    | N                       |                        | See comments       | N [1]           |
| Laparoscopic                |                   |   |   |     |     |                      |                         |                        |                    |                 |
| Musculo-skeletal            |                   |   |   |     |     |                      |                         |                        |                    |                 |
| Conventional                |                   |   |   |     |     |                      |                         |                        |                    |                 |
| Musculoskeletal Superficial |                   |   |   |     |     |                      |                         |                        |                    |                 |
| Other (specify)             |                   |   |   |     |     |                      |                         |                        |                    |                 |

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

Additional Comments: [1]: This probe can be used to acquire volumetric datasets from which any 2D tomographic plane can be then visualized. Applicable combined modes: B+M+PW+CFM+PD

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

concurrency of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

*David C. Seymour*  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal, ENT,  
 and Radiological Devices  
 510(k) Number K982444

K982444

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:

| 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             |                   | N | N | N   | N   | N                 |                      |                        | See comments       |                 |
| 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: / Applicable combined modes: B+M+PW+CW+CFM

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

concurrency of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

*David A. Segerson*  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal, ENT,  
 and Radiological Devices  
 510(k) Number K982444

Diagnostic Ultrasound Indications for Use Form

Transducer: TRT12

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<br>CFM | Amplitude Doppler<br>PD | Color Velocity Imaging | Combined (specify) | Other (specify) |
| Ophthalmic                  |                   |   |   |     |     |                      |                         |                        |                    |                 |
| Fetal                       |                   |   |   |     |     |                      |                         |                        |                    |                 |
| Abdominal                   |                   |   |   |     |     |                      |                         |                        |                    |                 |
| Intraoperative (specify)    |                   |   |   |     |     |                      |                         |                        |                    |                 |
| Intraoperative Neurological |                   |   |   |     |     |                      |                         |                        |                    |                 |
| Pediatric                   |                   |   |   |     |     |                      |                         |                        |                    |                 |
| Small Organ (specify) [1]   |                   |   |   |     |     |                      |                         |                        |                    |                 |
| Neonatal Cephalic           |                   |   |   |     |     |                      |                         |                        |                    |                 |
| Adult Cephalic              |                   |   |   |     |     |                      |                         |                        |                    |                 |
| Cardiac                     |                   |   |   |     |     |                      |                         |                        |                    |                 |
| Transesophageal             |                   |   |   |     |     |                      |                         |                        |                    |                 |
| Transrectal                 |                   | P | P | P   |     | P                    | P                       |                        | See comments       |                 |
| Transvaginal                |                   | P | P | P   |     | P                    | P                       |                        | See comments       |                 |
| 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 (K953716).

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

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

concurrency of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

*David A. Seymour*  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal, ENT,  
 and Radiological Devices  
 510(k) Number K982444