

AUG 23 1999

510(k) Premarket Notification  
Tissue Harmonic Imaging

UM 400C/ SA 6000C Ultrasound System

P144

K992470

**510(K) SUMMARY OF SAFETY AND EFFECTIVENESS**

This summary of safety and effectiveness is provided as part of this Premarket Notification in compliance with 21 CFR, Part 807, Subpart E, Section 807.92.

**1) Submitter's name, address, telephone number, contact person:**

Advanced Technology Laboratories, Inc.  
P.O. Box 3003  
Bothell, WA 98031-3003  
Vice President, Worldwide Quality & Regulatory Affairs  
Telephone: (425) 487-7602

Prepared: August 23, 1999

**2) Name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name, if known:**

Common/Usual Name:

Diagnostic Ultrasound System and Accessories

Proprietary Name:

Ultramark® 400C Diagnostic Ultrasound System and Transducers.

Also called: SonoAce 6000C Diagnostic Ultrasound System and Transducers.

| <u>Classification Names:</u>             | <u>FR Number</u> | <u>Product Code</u> |
|--|------------------|---------------------|
| Ultrasound Pulsed Echo Imaging System    | 892.1560         | 90-IYO              |
| Ultrasonic Pulsed Doppler Imaging System | 892.1550         | 90-IYN              |
| Diagnostic Ultrasound Transducer         | 892.1570         | 90-ITX              |

**3) Identification of the predicate or legally marketed device:**

Advanced Technology Laboratories, Inc. believes that the UM 400C/ SA 6000C Ultrasound System is substantially equivalent to the currently marketed SA 8800/HDI® 1500 system (K974269).

**4) Device Description:**

The UM 400C/SA 6000C system is a general purpose, mobile, software controlled, diagnostic ultrasound system. Its function is to acquire ultrasound data and to display the data as B-mode, M-mode, Color-Flow Doppler, Pulsed (PW) Doppler, Power Doppler, 3D, Tissue Harmonic Imaging or in a combination of these modes. M-mode uses the sweep display method which has its images flow from the left to the right on the monitor. The UM 400C/SA 6000C also gives the operator the ability to measure anatomical structures and offers analysis packages that provide information that is used to make a diagnosis by competent health care professionals. The system has real time acoustic output display with two basic indices, a mechanical index and a thermal index, which are both automatically displayed.

Nine different models of transducers are available and any two may be connected at the same time. In addition to the initial operational settings for each transducer preprogrammed in the system, user-customized parameter settings for each transducer may be inserted by the operator and stored for recall as needed via the system control panel. Customization includes transmit focusing, filtering, image enhancement processing, dynamic window curve selection. Controls are also provided to select display format (single and various combinations), to activate zoom features, and to utilize the cine loop function.

The UM 400C/SA 6000C system uses digital beamforming technology, and supports a variety of Linear and Convex probes for a wide variety of applications. It is a diagnostic ultrasound scanner, which provides high resolution, high penetration performance, and various measurement functions. Probes are supported in frequencies from 2.0 MHz to 9.0 MHz.

The system can be used to measure distances and calculate areas, circumferences and volumes, as well as calculate the date of delivery by using BPD (biparietal diameter), OFD (occipito-frontal diameter), HC (head circumference), AC (abdominal circumference), AD (abdominal diameter), FL (femur length), CRL (crown rump length), APTD (anteroposterior trunk diameter), TTD (transverse trunk diameter), GS (gestational sac), LMP (last menstrual period.), Cardiac Analysis and Vascular Analysis.

Biopsy guidelines are provided on screen to assist in the collection of tissue samples, using biopsy guide adapters offered as an optional accessory. The UM 400C/SA 6000C supports the Cine function (capable of storing up to 64 sequential images) and real-time zoom function to the region-of-interest. The system provides the ability to perform remote viewing of images, without compression, via a Dicom 3.0 compatible output. Management of patient history is possible by

image-filing function. High-resolution images are provided by utilizing a technology called digital dynamic receive focusing.

The UM 400C/SA 6000C has been designed to meet the following electromechanical safety standards:

- UL 2601-1, Underwriters Laboratories Standards, Medical Electrical Equipment
- C22.2 No. 601.1, Canadian Standards Association, Medical Electrical Equipment
- declaration of the acoustic output of medical diagnostic ultrasonic equipment
- EN 60601-1-2 (IEC 601-1-2,) European Norm, Collateral Standard: Electromagnetic Compatibility

**5) Intended Use:**

Ultramark 400C/ SonoAce 6000C intended uses as defined FDA guidance documents are:

- Fetal (includes infertility monitoring of follicle development)
- Abdominal
- Intra-operative (abdominal organs and peripheral vessel, neurological)
- Pediatric
- Small Organ
- Neonatal Cephalic
- Adult Cephalic
- Cardiac
- Trans-Rectal
- Trans-Vaginal
- Peripheral-Vascular
- Muscular-Skeletal (conventional, superficial)

Typical examinations performed using the system are:

- General abdominal and pelvic studies including organ surveys, assessment, and retro-peritoneal cavity studies.
- Study of small parts including breasts, shoulders, thyroid, and the abdominal wall.
- Pediatric scans of organs and bony structures.
- Peripheral vascular applications including carotid arteries, legs, arms, feet, and penile artery.
- Monitoring procedures for infertility studies (other than in vitro fertilization).
- First, second and third trimester pregnancy studies.
- Prostate, prostate biopsy guidance, and rectal wall studies.
- Neonatal head studies.
- Transcranial studies of middle cerebral arteries, internal carotid artery, and vertebral arteries.
- Cardiac studies in adults and children.
- Biopsy guidance for tissue or fluid sampling.
- Conventional podiatry scans.
- Intraoperative application including soft tissue structures.

**6) Technological Characteristics:**

This device operates identical to the predicate devices in that piezoelectric material in the transducer is used as an ultrasound source to transmit sound waves into the body. Sound waves are reflected back to the transducer and converted to electrical signals that are processed and displayed as a 2D and M-mode, Spectral Doppler, Color Doppler, Power Doppler, 3D, or Tissue Harmonic Imaging images. Transducer patient contact materials are biocompatible.

The device's acoustic output limits are:

All Applications:

|             |                        |           |
|-------------|------------------------|-----------|
| TIS/TIB/TIC | 0.0 – 5.0              | (Range)   |
| ISPTA       | 720 mW/cm <sup>2</sup> | (Maximum) |
| MI          | 1.9                    | (Maximum) |

The limits are the same as predicate Track 3 devices.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

AUG 23 1999

Mr. Terrence J. Sweeney  
Vice President, Worldwide Quality and Regulatory Affairs  
ATL Ultrasound  
Post Office Box 3003  
Bothel, Washington 98041-3303

Re: K992470  
Trade Name: Ultramark® 400C/Sonoace 6000C Diagnostic  
Ultrasound System with Tissue Harmonic Imaging (THI)  
Regulatory Class: II  
21 CFR §892.1560/Procode: 90 IYO  
Dated: July 23, 1999  
Received: July 26, 1999

Dear Mr. Sweeney:

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 transducer intended for use with the Ultramark® 400C/Sonoace 6000C Diagnostic Ultrasound System with Tissue Harmonic Imaging (THI), as described in your premarket notification:

Transducer Model Number

C3-7 Curved Linear Array 4.5 MHz/60R/60D/128 elements

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 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 - Mr. Terrence J. Sweeney

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

Sincerely yours,



CAPT Daniel G. 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(s)

**4.3 INDICATIONS FOR USE**

**DIAGNOSTIC ULTRASOUND INDICATIONS STATEMENT**

510(k) Number: K992470

System: Ultramark® 400C/SonoAce 6000C Ultrasound System

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

| Clinical Application   |                                       | Mode of Operation (*includes simultaneous B-mode) |   |     |     |                |                   |               |
|------------------------|---------------------------------------|---|---|-----|-----|----------------|-------------------|---------------|
| General (Track I only) | Specific (Tracks I & III)             | B   | M | PWD | CWD | Color Doppler* | Combined* (Spec.) | Other (Spec.) |
| Ophthalmic             | Ophthalmic                            |   |   |     |     |                |                   |               |
| Fetal Imaging & Other  | Fetal (See Note 3)                    | P   | P | P   |     | P              | Note 1            | Notes 2, 5, 6 |
|                        | Abdominal                             | P   | P | P   |     | P              | Note 1            | Notes 2, 5, 6 |
|                        | Intra-operative (Abdominal, vascular) | P   | P | P   |     | P              | Note 1            | Notes 2, 5    |
|                        | Intra-operative (Neuro.)              | P   | P | P   |     | P              | Note 1            | Note 5        |
|                        | Laparoscopic                          |   |   |     |     |                |                   |               |
|                        | Pediatric                             | P   | P | P   |     | P              | Note 1            | Notes 2, 5, 6 |
|                        | Small Organ (See Note 4)              | P   | P | P   |     | P              | Note 1            | Notes 2, 5, 6 |
|                        | Neonatal Cephalic                     | P   | P | P   |     | P              | Note 1            | Note 5        |
|                        | Adult Cephalic                        | P   | P | P   |     | P              | Note 1            | Note 5        |
|                        | Trans-rectal                          | P   | P | P   |     | P              | Note 1            | Notes 2, 5    |
|                        | Trans-vaginal                         | P   | P | P   |     | P              | Note 1            | Notes 2, 5    |
|                        | Trans-urethral                        |   |   |     |     |                |                   |               |
|                        | Trans-esoph. (non-Card.)              |   |   |     |     |                |                   |               |
|                        | Musculo-skel. (Convent.)              | P   | P | P   |     | P              | Note 1            | Notes 2, 5    |
|                        | Musculo-skel. (Superfic.)             | P   | P | P   |     | P              | Note 1            | Notes 2, 5    |
| Intra-luminal          |                                       |   |   |     |     |                |                   |               |
| Other (spec.)          |                                       |   |   |     |     |                |                   |               |
| Other (spec.)          |                                       |   |   |     |     |                |                   |               |
| Cardiac                | Cardiac Adult                         | P   | P | P   |     | P              | Note 1            | Note 5        |
|                        | Cardiac Pediatric                     | P   | P | P   |     | P              | Note 1            | Note 5        |
|                        | Trans-esophagaal (card)               |   |   |     |     |                |                   |               |
|                        | Other (spec.)                         |   |   |     |     |                |                   |               |
| Peripheral Vessel      | Peripheral vessel                     | P   | P | P   |     | P              | Note 1            | Note 5        |
|                        | Other (spec.)                         |   |   |     |     |                |                   |               |

N= new indication; P= previously cleared by FDA in K981510 & K990970; E= added under Appendix E

**Additional Comments:**

Color Doppler includes Color Amplitude Doppler (P)

Note 1: PWD/Color Doppler, PWD/Power Doppler (P)

Note 2: Includes imaging for guidance of biopsy (P)

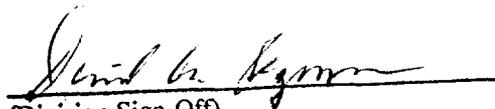
Note 3: Includes infertility monitoring of follicle development (P)

Note 4: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients (P)

Note 5: 3D Imaging (P)

Note 6: Tissue Harmonic Imaging (N)

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 K992470

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) Number: **K992470**  
 System: Ultramark® 400C/ SonoAce 6000C Ultrasound System  
 Scanhead: C3-7 Curved Linear Array 4.5 MHz/60R/60D/128 elements  
 Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

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| General (Track I only) | Specific (Tracks I & III)             | B   | M | PWD | CWD | Color Doppler* | Combined* (Spec.) | Other (Spec.) |
| Ophthalmic             | Ophthalmic                            |   |   |     |     |                |                   |               |
| Fetal Imaging & Other  | Fetal (See Note 3)                    | N   | N | N   |     | N              | Note 1            | Notes 2, 5, 6 |
|                        | Abdominal                             | N   | N | N   |     | N              | Note 1            | Notes 2, 5, 6 |
|                        | Intra-operative (Abdominal, vascular) |   |   |     |     |                |                   |               |
|                        | Intra-operative (Neuro.)              |   |   |     |     |                |                   |               |
|                        | Laparoscopic                          |   |   |     |     |                |                   |               |
|                        | Pediatric                             | N   | N | N   |     | N              | Note 1            | Notes 2, 5, 6 |
|                        | Small Organ (See Note 4)              | N   | N | N   |     | N              | Note 1            | Notes 2, 5, 6 |
|                        | Neonatal Cephalic                     |   |   |     |     |                |                   |               |
|                        | Adult Cephalic                        |   |   |     |     |                |                   |               |
|                        | Trans-rectal                          |   |   |     |     |                |                   |               |
|                        | Trans-vaginal                         |   |   |     |     |                |                   |               |
|                        | Trans-urethral                        |   |   |     |     |                |                   |               |
|                        | Trans-esoph. (non-Card.)              |   |   |     |     |                |                   |               |
|                        | Musculo-skel. (Convent.)              |   |   |     |     |                |                   |               |
|                        | Musculo-skel. (Superfic.)             |   |   |     |     |                |                   |               |
| Intra-luminal          |                                       |   |   |     |     |                |                   |               |
| Other (spec.)          |                                       |   |   |     |     |                |                   |               |
| Cardiac                | Cardiac Adult                         |   |   |     |     |                |                   |               |
|                        | Cardiac Pediatric                     |   |   |     |     |                |                   |               |
|                        | Trans-esophageal (card.)              |   |   |     |     |                |                   |               |
|                        | Other (spec.)                         |   |   |     |     |                |                   |               |
| Peripheral Vessel      | Peripheral vessel                     |   |   |     |     |                |                   |               |
|                        | Other (spec.)                         |   |   |     |     |                |                   |               |

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

Additional Comments:

Color Doppler includes Color Amplitude Doppler

Note 1: PWD/Color Doppler, PWD/Power Doppler (N)

Note 2: Includes imaging for guidance of biopsy (N)

Note 3: Includes infertility monitoring of follicle development (N)

Note 4: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients (N)

Note 5: 3D Imaging (N)

Note 6: Tissue Harmonic Imaging (N)

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

  
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