

MAR 24 2000

510(k) Premarket Notification
MPT7-4 Scanhead

K 994373
HDI® 1500/SA 8800 Ultrasound System

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

Terrence J. Sweeney
Vice President, Quality and Regulatory Affairs

Telephone: (425) 487-7602

Prepared: December 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
Multiplane Transesophageal Ultrasound Transducer

Proprietary Name:

HDI® 1500 Diagnostic Ultrasound System and Transducers.
Also called SonoAce 8800 (SA 8800) Diagnostic Ultrasound System and Transducers.
Multiplane Transesophageal 7-4 Transducer (MPT7-4.)

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

3) Identification of the predicate or legally marketed device:

ATL believes that the MPT 7-4 scanhead to be used with the HDI 1500/SA 8800 Ultrasound system is substantially equivalent to the currently marketed MPT7-4 transducer marketed with the ATL HDI 5000 System, K961459, and the Olympus Ultrasonic Endoscope (K963023).

4) Device Description:

The HDI 1500/SA 8800 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, Continuous (CW) Doppler, Pulsed (PW) Doppler and Power Doppler, or as a combination of these modes. The HDI 1500/SA 8800 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 HDI 1500/SA 8800 has real time acoustic output display with two basic indices, a mechanical index and a thermal index, which are both automatically displayed.

Eleven different models of transducers are available and any three 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 HDI® 1500/SA 8800 system uses digital beamforming technology, and supports a variety of Linear, Convex, Phased Array and Static probes for a wide variety of applications. It is an ultrasound scanner, which provides high resolution, high penetration performance, and various measurement functions. Probes are supported in frequencies from 2.0 MHz to 12.0 MHz. These probes can be applied to a variety of clinical applications such as abdominal, obstetrical, cerebrovascular, peripheral vascular, gynecological and fertility, small parts, intraoperative, vascular, abdominal surgery, conventional musculoskeletal, transcranial Doppler, pediatric general imaging, prostate, adult cardiology, pediatric cardiology and transesophageal (cardiac and non-cardiac). The same clinical uses were cleared for the predicate devices, ATL's 5000 (K961459) and the Olympus GF Type UM30P Ultrasonic Endoscope (K963023.)

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.

The MPT7-4 transducer is a multi-element ultrasound transducer mounted on a gastroscopic articulating device. The transducer elements are electronically time- and phase-coordinated to generate a steered and focused ultrasound beam, which produces a high-resolution real-time image. The transducer allows a circular continuum of tomographic images within a 185-degree arc without moving the transducer.

The MPT7-4 has a transducer array that rotates along an axis perpendicular to the axis of the probe shaft. At 0-degree orientation, the acquired tomographic plane is equivalent to the transverse plane, and at approximately 90-degree orientation, sagittal plane images can be obtained with the transducer array about 30 cm from the patient's teeth. The transducer array can be rotated up to 180 degrees, which provides a mirror image of the 0-degree orientation. Multiple tomographic image planes are continuously selected by rotating the transducer array without significant manipulation of the MPT7-4 transducer.

The MPT7-4 transducer is used for cardiac and non-cardiac transesophageal 2D and M-mode imaging, pulsed-wave and continuous-wave Doppler, and Color Doppler imaging.

Biopsy guidelines are provided on screen to assist in the collection of tissue samples, using biopsy guide adapters offered as an optional accessory. The Biopsy guides are the same as those previously cleared for the predicate device, ATL's HDI 5000 system (K961459). The operating Modes of HDI 1500/SA 8800 system are B-Mode, M, Color-Flow Doppler, Continuous wave (CW) Doppler, Pulsed (PW) Doppler, Power Doppler, or as 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 HDI 1500/SA 8800 system 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 HDI 1500/SA 8800 has been designed to meet the following electromechanical safety standards:

- EN 60601-1 (IEC 601-1,) European Norm, Medical Electrical Equipment
- UL 2601-1, Underwriters Laboratories Standards, Medical Electrical Equipment
- C22.2 No. 601.1, Canadian Standards Association, Medical Electrical Equipment
- CEI/IEC 1157:1992, International Electrotechnical Commission, Requirements for the declaration of the acoustic output of medical diagnostic ultrasonic equipment
- EN 60601-1-2 (IEC 601-1-2,) European Norm, Collateral Standard: Electromagnetic Compatibility
- Compliant with the European Medical Device Directive Certificate issued by TUV.

4) **Intended Use:**

HDI® 1500/SA 8800 intended uses as defined FDA guidance documents are:

- Abdominal
- Obstetrical
- Cerebrovascular
- Peripheral vascular
- Gynecological and fertility
- Small parts
- Intraoperative vascular
- Abdominal surgery
- Musculoskeletal (conventional)
- Transcranial Doppler
- Pediatric general imaging
- Prostate
- Adult cardiology
- Pediatric cardiology
- Transesophageal (Cardiac and Non-cardiac)

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.
- Monitoring of cardiac function during procedures using transesophageal echocardiography.
- General diagnostic and outpatient imaging of difficult to image patients using transesophageal applications.
- 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, Continuous wave Doppler, Spectral Doppler, Color Doppler, Power Doppler, 3D images. Scanhead patient contact materials are biocompatible.

The device's acoustic output limits are:

All Applications:	(Maximum Range)
ISPTA	720 mW/cm ²
MI	1.9

The limits are the same as predicate Track 3 devices.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 24 2000

Mr. Terrence J. Sweeney
Vice President, Worldwide Quality and Regulatory Affairs
ATL Ultrasound
22100 Bothell Everett Highway
P. O. Box 3003
Bothell, Washington 98041-3003

Re: K994373

Multiplane Transesophageal 7-4 Transducer (MPT7-4) for use with the HDI® 1500/SonoAce 8800
Diagnostic Ultrasound System
Regulatory Class: II
21CFR892.1570/Procode: 90 ITX
Dated: December 23, 1999
Received: December 27, 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 Multiplane Transesophageal 7-4 Transducer (MPT7-4) intended for use with the HDI® 1500/SonoAce 8800 Diagnostic Ultrasound System, as described in your premarket notification.

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.

Page -2- Mr. Sweeney

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

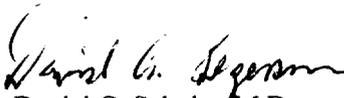
Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

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

Sincerely yours,

for 
Daniel G. Schultz, M.D.
Captain, USPHS

Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosures

K99 4373

4.3 INDICATIONS FOR USE

DIAGNOSTIC ULTRASOUND INDICATIONS STATEMENT

510(k) Number:

System: HDI 1500/SA 8800 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	P	Note 1	Notes 2, 4, 7, 8
	Abdominal	P	P	P	P	P	Note 1	Notes 2, 4, 7, 8
	Intra-operative (See Note 6)	P	P	P		P	Note 1	Notes 2, 4, 7, 8
	Intra-operative (Neuro.)	P	P	P	P	P	Note 1	Notes 4, 8
	Laparoscopic							
	Pediatric	P	P	P	P	P	Note 1	Notes 2, 4, 7, 8
	Small Organ (See Note 5)	P	P	P		P	Note 1	Notes 2, 4, 7, 8
	Neonatal Cephalic	P	P	P	P	P	Note 1	Notes 4, 8
	Adult Cephalic	P	P	P	P	P	Note 1	Notes 4, 7, 8
	Trans-rectal	P	P	P		P	Note 1	Notes 2, 7, 8
	Trans-vaginal	P	P	P		P	Note 1	Notes 2, 7, 8
	Trans-urethral							
	Trans-esoph. (non-Cardiac)	N	N	N	N	N	Note 1 (N)	Notes 4, 7, 8 (N)
	Musculo-skel. (Convent.)	P	P	P		P	Note 1	Notes 2, 7, 8
	Musculo-skel. (Superfic.)	P	P	P		P	Note 1	Notes 2, 7, 8
Intra-luminal								
Other (spec.)								
Cardiac	Cardiac Adult	P	P	P		P	Note 1	Notes 4, 7, 8
	Cardiac Pediatric	P	P	P		P	Note 1	Notes 4, 7, 8
	Trans-esophageal (Cardiac)	N	N	N	N	N	Note 1 (N)	Notes 4, 7, 8 (N)
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P	E	P	Note 1	Note 4, 8
	Other (spec.)							

N= new indication; P= previously cleared by FDA in K974269; E= added under Appendix E

Additional Comments:

Color Doppler includes Color Amplitude Doppler (P)

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

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

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

Note 4: Color M-mode (P)

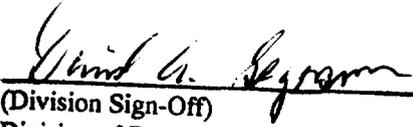
Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients (P)

Note 6: Abdominal organs and peripheral vessel (P)

Note 7: Tissue Harmonic Imaging (THI) (P)

Note 8: 3D Imaging (P)

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 K994373

K994373

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) Number:

System: HDI 1500/SA 8800 Ultrasound System

Transducer: MPT7-4 /7.0-4.0 MHz/Phased Array

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)								
	Abdominal								
	Intra-operative (Abdominal, vascular)								
	Intra-operative (Neuro.)								
	Laparoscopic								
	Pediatric								
	Small Organ (See Note 5)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Cardiac)		N	N	N	N	N	Note 1 (N)	Notes 4,7, 8 (N)
	Musculo-skel. (Convent.)								
	Musculo-skel. (Superfic.)								
Intra-luminal									
Other (spec.)									
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Trans-esophageal (Cardiac)		N	N	N	N	Note 1 (N)	Notes 4,7, 8 (N)	
	Other (spec.)								
Peripheral Vessel	Peripheral vessel								
	Other (spec.)								

N= new indication; P= previously cleared by FDA in K974269; E= added under Appendix E

Additional Comments:

Color Doppler includes Color Amplitude Doppler

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

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

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

Note 4: Color M-mode (P)

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients (P)

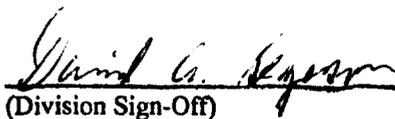
Note 6: Abdominal organs and peripheral vessel (P)

Note 7: Tissue Harmonic Imaging (THI) (P)

Note 8: 3D Imaging

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 K994373