K991671

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:

Terrence J. Sweeney
Vice President, Worldwide Quality and Regulatory Affairs
Advanced Technology Laboratories, Inc.
P.O. Box 3003
Bothell, WA 98041-3003
(206) 487-7602

Date prepared: May 14, 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 with Accessories

Proprietary Name

HDI® 5000 Ultrasound System

Classification Names

Ultrasonic Pulsed Doppler Imaging System, Product Code 90 IYN, 21 CFR 892.1550

Diagnostic Ultrasonic Scanhead, Product Code 90 ITX, 21 CFR 892.1570

Ultrasonic Pulsed Echo Imaging System, Product Code 90IYO, 21 CFR 892.1560

3) Identification of the predicate or legally marketed device:

Advanced Technology Laboratories, Inc. believes that the Advanced Image Processing feature on the HDI 5000 system is substantially equivalent to the currently marketed General Electric System Five.

4) Device Description:

The HDI 5000 system is a general purpose, mobile, software-controlled, diagnostic ultrasound system. Its function is to acquire ultrasound data and display it on a monitor in 2D, M-mode, 2D Color Doppler, M-mode Color Doppler, Continuous Wave Doppler (CW), Pulsed (PW) Doppler, Color Power Angio (CPA), 3D, or in a combination of modes. The HDI 5000 system 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 5000 has an output display with two basic indices, a mechanical index and a thermal index, which are both automatically displayed.

The HDI 5000 system is designed to accept a large selection of scanheads with up to three array scanheads and one static probe being connected to the system at any one time. The operator may select among the scanheads by means of a control located on the system control panel. All actions affecting the performance of the scanhead are activated from the main system control panel.

Advanced Image Processing is a feature upgrade to the HDI 5000 Ultrasound System that adds enhanced DSP image processing hardware and proprietary software algorithms to improve 2D image quality. The sub-systems affected by the software algorithms include the beamformer, signal processing, and image processing modules. The enhanced DSP hardware approximately doubles the image processing power of the HDI 5000 system, allowing processed images to be generated in real time with no loss of frame rate. The benefits of Advanced Image Processing include enhanced contrast resolution, improved tissue texture definition, clutter reduction, and better definition and continuity of tissue interfaces.

The HDI 5000 system is designed to accept scanheads of the following types and frequency:

frequency range:	2.0 - 10.0 MHz
scanhead types:	Linear array
	Curved linear array
	Phased array
	Static probes

Specific operating conditions (frame rate, line density, center frequency, number of active elements etc.) are automatically optimized by the system software in response to user inputs such as field of view, focal depth, image quality, power etc.

The HDI 5000 system has been designed to meet the following electromechanical safety standards:

- IEC 601-1, International Electrotechnical Commission, 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
- IEC 601-1-2, Collateral Standard: Electromagnetic Compatibility

5) Intended Use:

The HDI 5000 system is intended for ophthalmic, fetal, abdominal, intraoperative, pediatric, small organ, adult and neonatal cephalic, cardiac, transesophageal, transrectal, transvaginal, peripheral vessel, laparoscopic, and musculoskeletal (conventional and superficial) intended uses as defined in the FDA guidance document.

Typical examinations using the HDI 5000 system are:

- General abdominal and pelvic studies including organ surveys, blood flow assessment, and retroperitoneal cavity studies.
- Study of small parts and superficial structures including breasts, shoulders, thyroid/parathyroid, and the abdominal wall.
- Pediatric scans of organs, superficial, 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.
- Biopsy guidance for tissue or fluid sampling.
- Assessment of cardiac muscle, coronary arteries and great vessels during cardiac surgery
- Study of myocardial function in adults
- Study of eye anatomy including blood flow in retinal vessels and branches

- Study of the esophagus, stomach, biliary sytem, pancreas and gastrointestinal tract using endoscopic probe
- Study of abdominal and pelvic organs and masses using laparoscopic probe
- Examination of organs, masses and vessels during surgical procedures
- Study of muscles, ligaments, nerve bundles and connective tissue

6) Technological Characteristics:

This device operates identical to the predicate device 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 images. Doppler shift caused by blood flow is displayed as Color Flow, or as spectrum analysis. The modes of this device (2D, M-mode, Color Flow, Color M-mode, Color Power Angio, and Pulsed Doppler) are the same as predicate devices identified in item 3. Scanhead patient contact materials are biocompatible.

This device conforms to the Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment (AIUM/NEMA, 1992) for an on-screen display feature that provides information on potential thermal and cavitation bioeffect mechanisms. A user education program provides additional information so users may moderate the system's acoustic output in accordance with the ALARA (as low as reasonably achievable) principle.

The device's acoustic output limits are:

All Applications Other Than Ophthalmic:

I_{SPTAd}	720 mW/cm2 (Maximum)	
TIS/TIB/TIC	0.1 - 6.0	(Range)
Mechanical Index (MI)	1.9	(Maximum)
I_{SPPAd}	0 - 700 W/cm2	(Range)

Ophthalmic Applications:

I_{SPTAd}	50 mW/cm^2	(Maximum)
TIS at Surface / Thermal Index (TIC)	0.1 - 1.0	(Range)
Mechanical Index (MI)	.23	(Maximum)
I_{SPPAd}	0 - 50 W/cm^2	(Range)

The limits are same as predicate Track 3 devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 18 1999

Terrence J. Sweeney
ATL Ultrasound
22100 Bothell Everett Highway
Bothell, WA 98401-3003

Re: K991671
Trade Name: HDI® 5000 Diagnostic Ultrasound System with Advanced Image Processing
Regulatory Class: II
Product Code: 90 IYO 21CFR 892.1560
Dated: May 14, 1999
Received: May 17, 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 transducers intended for use with the HDI® 5000 Diagnostic Ultrasound System with Advanced Image Processing, as described in your premarket notification:

Transducer Model Number

L12-5/12.5-5.0 MHz/38mm/Linear Array
L12-5/12.5-5.0 MHz/50mm/Linear Array

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

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".

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

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)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

510(k) Number: K991671
System: HDI® 5000 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	P		P	P	P	P	Note 5
Fetal Imaging & Other	Fetal	P	P	P	P	P	P	
	Abdominal	P	P	P	P	P	P	
	Intra-operative (Abdominal, vascular)	P		P	P	P	P	Notes 2, 4, 5
	Intra-operative (Neuro.)	P		P	P	P	P	
	Laparoscopic	P		P	P	P	P	
	Pediatric	P	P	P	P	P	P	Notes 2, 4, 5
	Small Organ (breast, thyroid, testicles)	P	P	P	P	P	P	Notes 2, 4, 5
	Neonatal Cephalic	P	P	P	P	P	P	
	Adult Cephalic	P	P	P	P	P	P	
	Trans-rectal	P	P	P		P	P	
	Trans-vaginal	P	P	P	P	P	P	
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)	P	P	P		P	P	Notes 2, 4, 5
	Musculo-skel. (Superfic.)	P	P	P		P	P	Notes 2, 4, 5
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult	P	P	P	P	P	P	
	Cardiac Pediatric	P	P	P	P	P	P	
	Trans-esophageal (card.)	P	P	P	P	P	P	
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P	P	P	P	Notes 4, 5
	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
Note 2: Includes imaging for guidance of biopsy
Note 3: For example: thyroid, parathyroid, breast, scrotum and penis in adult pediatric and neonatal patients.
Note 4: Color M-mode
Note 5: Advanced Image Processing

Prescription Use (Per 21 CFR 801.109)

David A. Seguson

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K991671

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

510(k) Number: K991671
System: HDI® 5000 Ultrasound System
Scanhead: L12-5/12.5-5.0 MHz/38mm/Linear 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	P	P	P		P	Note 1	Note 5
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Abdominal, vascular)	P	P	P		P	Note 1	Notes 2, 4, 5
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note 1	Notes 2, 4, 5
	Small Organ See Note 3	P	P	P		P	Note 1	Notes 2, 4, 5
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)	P	P	P		P	Note 1	Notes 2, 4, 5
	Musculo-skel. (Superfic.)	P	P	P		P	Note 1	Notes 2, 4, 5
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	Note 1	Notes 4, 5
	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 Dop., PWD/Power Doppler (previously cleared)
Note 2: Includes imaging for guidance of biopsy (previously cleared)
Note 3: For example: thyroid, parathyroid, breast, scrotum and penis in adult pediatric and neonatal patients.
Note 4: Color M-mode (previously cleared)
Note 5: Advanced Image Processing

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K991671

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

510(k) Number: K991671
System: HDI® 5000 Ultrasound System
Scanhead: L12-5/12.5-5.0 MHz/50mm/Linear 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	E	E	E		E	Note 1	Note 5
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Abdominal, vascular)	E	E	E		E	Note 1	Notes 2, 4, 5
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	E	E	E		E	Note 1	Notes 2, 4, 5
	Small Organ See Note 3	E	E	E		E	Note 1	Notes 2, 4, 5
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)	E	E	E		E	Note 1	Notes 2, 4, 5
	Musculo-skel. (Superfic.)	E	E	E		E	Note 1	Notes 2, 4, 5
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	E	E	E		E	Note 1	Notes 4, 5
	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 Dop., PWD/Power Doppler
Note 2: Includes imaging for guidance of biopsy
Note 3: For example: thyroid, parathyroid, breast, scrotum and penis in adult pediatric and neonatal patients.
Note 4: Color M-mode
Note 5: Advanced Image Processing

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K991671