

APR - 2 1998

ATTACHMENT 1
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
Atlantis Diagnostics International, Inc. (ADII)
19015 North Creek Parkway, Suite 105
Bothell WA 98011
(425) 487-7602

Date prepared: March 3, 1998

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® 1000 Diagnostic Ultrasound System

Classification Names:

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

Diagnostic Ultrasonic Transducer, 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:

ADII believes that HDI 1000 system is substantially equivalent to the currently-marketed ATL HDI 3000 diagnostic ultrasound system, ATL Ultramark® 9 diagnostic ultrasound system, Atlantis Atlas 1.0 system, Storz Renaissance A/B Scan, and the HDI 5000 diagnostic ultrasound system.

4) Device Description:

This 510(k) adds the musculoskeletal applications (superficial and conventional) to the HDI 1000 system.

The HDI 1000 system is a general purpose, mobile, software-controlled, diagnostic ultrasound systems with an on-screen display for thermal and mechanical values related to potential bioeffect mechanisms. The HDI 1000 system functions by acquiring ultrasound data and displaying it on a monitor in

2-D, M-mode, 2-D Color Flow Doppler, Color M-mode, Color Power Angio, Pulsed (PW) Doppler or in a combination of modes. An audio presentation of pulsed Doppler information is also available on the systems. The systems also provide for the measurement of anatomical structures and for analysis packages that provide information that is used for clinical diagnostic purposes.

The HDI 1000 system is designed to accept a large selection of scanheads with up to two being connected to the system at any one time. The operator may select between the two 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.

The HDI 1000 system is designed to accept scanheads of the following types and frequency:

frequency range:	2.0 - 11.0 MHz
scanhead types:	flat linear array curved linear array phased array

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 1000 system been designed to meet the following electromechanical safety standards:

- EN 60601-1 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, Collateral Standard: Electromagnetic Compatibility

5) Intended Use:

The HDI 1000 system is intended for ophthalmic, fetal (OB/GYN), abdominal, intraoperative (abdominal organs, vasuclar, neurological,) pediatric, small organ, musculoskeletal (conventional, superficial,) neonatal cephalic, adult cephalic, cardiac, transrectal, transvaginal, and peripheral vessel indications for use.

Typical examinations shall include:

- General abdominal and pelvic studies including organ surveys and retro-peritoneal cavity studies.
- Study of small parts including breasts, penis, testes, thyroid/parathyroid and the abdominal wall.
- Pediatric scans of organs.

- Peripheral vascular applications including carotid arteries, legs, arms, feet, and penile artery.
- Monitoring procedures for infertility applications.
- First, second and third trimester pregnancy studies.
- Prostate, prostate biopsy guidance, and rectal wall studies.
- Neonatal cephalic 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.
- Ophthalmic studies of the eye and surrounding structures and studies to obtain blood flow information in the eye and surrounding structures.
- Conventional and superficial musculoskeletal studies.

6) Technological Characteristics:

This device operates identical to the predicate devices in that piezo 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 2-D and M-mode images. Doppler shift caused by blood flow is displayed as Color Flow, or as spectrum analysis. The modes of these devices (2-D, 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 and are also the same as the identified predicate devices.

These devices conform 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:

ISPTAd	720 mW/cm ²	(Maximum)
TIS/TIB/TIC	0.1 - 4.0	(Range)
Mechanical Index (MI)	1.9	(Maximum)
ISPPAd	0 - 700 W/cm ²	(Range)

Ophthalmic Applications:

ISPTAd	50 mW/cm ²	(Maximum)
Thermal Index (TIC)	0.1 - 1.0	(Range)
Mechanical Index (MI)	.23	(Maximum)
ISPPAd	0 - 50 W/cm ²	(Range)

The limits are same as predicate Track 3 devices.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 2 1998

Terrence J. Sweeney
Vice President
Worldwide Quality and Regulatory Affairs
Atlantis Diagnostics International, Inc.
19015 North Creek Parkway
Bothell, WA 98011

Re: K980860
HDI 1000 Diagnostic Ultrasound System
Dated: March 3, 1998
Received: March 5, 1998
Regulatory class: II
21 CFR 892.1560/Procode: 90 IYO
21 CFR 892.1550/Procode: 90 IYN
21 CFR 892.1570/Procode: 90 ITX

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 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. You may, therefore, market the device, subject to the general controls provisions Act (Act). The general controls provisions of the Act include requirements for registration, listing of devices, good manufacturing practices, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the HDI 1000 Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

CL10-5/10.0.5.0 MHz/Linear Array
L11-5/11.0.5.0 MHz/38mm/Linear Array
L19-5/9.0-5.0 MHz/38mm/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 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:

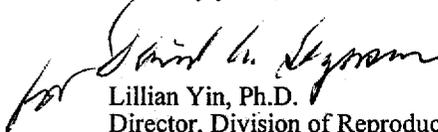
Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

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>".

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

Sincerely yours,



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

Indications Statement for System

510(k) Number: **K980860**
 Device Name: **HDI@1000 Ultrasound System**

Indications for Use: **Diagnostic ultrasound / Pulsed Doppler / Pulsed Echo imaging (specify) of the human body as follows:**

Mode of Operation (*includes simultaneous B-Mode)

Clinical Applications	A	B	M*	PWD*	CWD*	Color Doppler*	Power (Amp) Doppler*	Color Velocity Imaging	Combined (Specify)*	Other (Specify)
Ophthalmic		P		P		P	P			
Fetal		P	P	P		P	P		P (Note 1)	P (Note 2)
Abdominal		P		P		P	P		P (Note 1)	P (Note 2)
Intra-operative : Abdominal organs & vascular		P		P		P	P		P (Note 1)	P (Note 2)
Intra-operative Neurological		P		P		P	P		P (Note 1)	
Pediatric		P		P		P	P		P (Note 1)	P (Note 2)
Small Organ See Note 3		P		P		P	P		P (Note 1)	P (Note 2)
Neonatal Cephalic		P		P		P	P		P (Note 1)	
Adult Cephalic		P		P		P	P		P (Note 1)	
Cardiac		P	P	P		P	P		P (Note 1)	
Trans-esophageal										
Transrectal		P		P		P	P		P (Note 1)	P (Note 2)
Transvaginal		P	P	P		P	P		P (Note 1)	P (Note 2)
Transurethral										
Intavascular										
Peripheral vessel		P		P		P	P		P (Note 1)	
Laparoscopic										
Musculo-skeletal Conventional		N		N		N	N		N (Note 1)	
Musculo-skeletal Superficial		N		N		N	N		N (Note 1)	

Other Indications or Modes:

Note 1: PWD/CD, PWD/PAD

Note 2: Includes imaging for guidance of biopsy

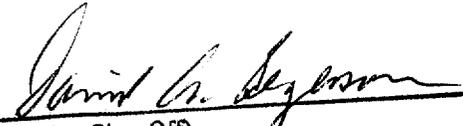
Note 3: Thyroid, parathyroid, breast, scrotum, penis in adult, pediatric and neonatal patients

P indicates previously cleared indication in K961073.

N indicates new indication.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)


 (Division Sign-Off)

Division of Reproductive, Abdominal, ENT,
 and Radiological Devices

510(k) Number K980860

Ultrasound Device Indications Statement

510(k) Number: **K980860**
 Device Name: **HDI@1000 Ultrasound System**
 Transducer: **CL10-5/10.0-5.0 MHz/Linear Array**

Indications for Use: **Diagnostic ultrasound / Pulsed Doppler / Pulsed Echo imaging**
 (specify) of the human body as follows:

Mode of Operation (*includes simultaneous B-Mode)

Clinical Applications	A	B	M*	PWD*	CWD*	Color Doppler*	Power (Amp) Doppler*	Color Velocity Imaging	Combined (Specify)*	Other (Specify)
Ophthalmic		P		P		P	P			
Fetal										
Abdominal										
Intra-operative : Abdominal organs & vascular		P		P		P	P		P (Note 1)	
Intra-operative Neurological										
Pediatric										
Small Organ See Note 2		P		P		P	P		P (Note 1)	
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intavascular										
Peripheral vessel										
Laparoscopic										
Musculo-skeletal Conventional		N		N		N	N		N (Note 1)	
Musculo-skeletal Superficial		N		N		N	N		N (Note 1)	

Other Indications or Modes:

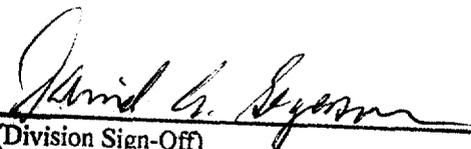
Note 1: PWD/CD, PWD/PAD

Note 2: Thyroid, parathyroid, breast, scrotum, penis in adult, pediatric and neonatal patients

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(Division Sign-Off)
 Division of Reproductive, Abdominal, ENT,
 and Radiological Devices

510(k) Number K980860

Ultrasound Device Indications Statement

510(k) Number: **K980860**
 Device Name: **HDI®1000 Ultrasound System**
 Transducer: **L11-5/11.0-5.0 MHz/38mm/Linear Array**

Indications for Use: **Diagnostic ultrasound / Pulsed Doppler / Pulsed Echo imaging**
 (specify) of the human body as follows:

Mode of Operation (*includes simultaneous B-Mode)

Clinical Applications	A	B	M*	PWD*	CWD*	Color Doppler*	Power (Amp) Doppler*	Color Velocity Imaging	Combined (Specify)*	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intra-operative : Abdominal organs, vascular		P		P		P	P		P (Note 1)	P (Note 2)
Intra-operative Neurological										
Pediatric		P		P		P	P		P (Note 1)	P (Note 2)
Small Organ See Note 3		P		P		P	P		P (Note 1)	P (Note 2)
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intavascular										
Peripheral vessel		P		P		P	P		P (Note 1)	
Laparoscopic										
Musculo-skeletal Conventional		N		N		N	N		N (Note 1)	
Musculo-skeletal Superficial		N		N		N	N		N (Note 1)	

Other Indications or Modes:

Note 1: PWD/CD, PWD/PAD

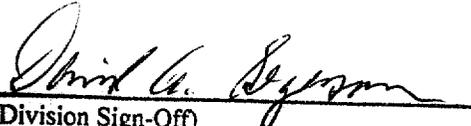
Note 2: Includes imaging for guidance of biopsy.

Note 3: Thyroid, parathyroid, breast, scrotum, penis in adult, pediatric and neonatal patients.

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Division of Reproductive, Abdominal, ENT,
 and Radiological Devices

510(k) Number K980860

Ultrasound Device Indications Statement

510(k) Number: **K980860**
 Device Name: **HDI®1000 Ultrasound System**
 Transducer: **LI9-5/9.0-5.0 MHz/38mm/Linear Array**

Indications for Use: **Diagnostic ultrasound / Pulsed Doppler / Pulsed Echo imaging**
 (specify) of the human body as follows:

Mode of Operation (*includes simultaneous B-Mode)

Clinical Applications	A	B	M*	PWD*	CWD*	Color Doppler*	Power (Amp) Doppler*	Color Velocity Imaging	Combined (Specify)*	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intra-operative: Abdominal organs, vascular		P		P		P	P		P (Note 1)	P (Note 2)
Intra-operative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel										
Laparoscopic										
Musculo-skeletal Conventional		N		N		N	N		N (Note 1)	N (Note 2)
Musculo-skeletal Superficial		N		N		N	N		N (Note 1)	N (Note 2)

Other Indications or Modes:

Note 1: PWD/CD, PWD/PAD

Note 2: Includes imaging for guidance of biopsy.

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David G. Segerson
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 Division of Reproductive, Abdominal, ENT,
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 510(k) Number K980860