

510(k) Premarket Notification
K961073

Atlantis Atlas 2.0 / Hitachi 2.0 Ultrasound Systems
Revision - February 13, 1997

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SECTION 10
510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

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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:*

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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

Atlas 2.0 Diagnostic Ultrasound System

Hitachi 2.0 Diagnostic 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 90IYD, 21 CFR 892.1560

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

ADII believes that Atlas 2.0 / Hitachi 2.0 are substantially equivalent to the currently-marketed ATL HDI 3000 diagnostic ultrasound system, ATL Ultramark® 9 HDI™ diagnostic ultrasound system, Atlantis Atlas 1.0 system and Storz Renaissance A/B Scan.

4) *Device Description:*

Atlas 2.0 / Hitachi 2.0 are general purpose, mobile, software-controlled, diagnostic ultrasound systems with an on-screen display for thermal and mechanical values related to potential bioeffect mechanisms. Their function is to acquire ultrasound data and display 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

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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 Atlas 2.0 / Hitachi 2.0 systems are 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 Atlas 2.0 / Hitachi 2.0 system is designed to accept scanheads of the following types and frequency:

- frequency range: 2.0 - 10.0 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.

Atlas 2.0 / Hitachi 2.0 have 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
- CE/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:*

Atlas 2.0 / Hitachi 2.0 are intended for cardiac, peripheral vascular, fetal imaging and other, and ophthalmic intended uses as defined FDA guidance documents.

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.

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- Ophthalmic studies of the eye and surrounding structures and studies to obtain blood flow information in the eye and surrounding structures.

6) *Technological Characteristics:*

These devices operate 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:

| | | |
|-----------------------|---------------------------|-----------|
| I_{SPTA_d} | 720 mW/cm ² | (Maximum) |
| TIS/TIB/TIC | 0.1 - 4.0 | (Range) |
| Mechanical Index (MI) | 1.9 | (Maximum) |
| I_{SPPA_d} | 0 - 700 W/cm ² | (Range) |

Ophthalmic Applications:

| | | |
|-----------------------|--------------------------|-----------|
| I_{SPTA_d} | 50 mW/cm ² | (Maximum) |
| Thermal Index (TIC) | 0.1 - 1.0 | (Range) |
| Mechanical Index (MI) | .23 | (Maximum) |
| I_{SPPA_d} | 0 - 50 W/cm ² | (Range) |

The limits are same as predicate Track 3 devices.