K961459

SECTION 8
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:

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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

Level 10 HDI 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 90~~IYD~~ 90IYO, 21 CFR 892.1560 BmM 3/17/97

3) Identification of the predicate or legally marketed device:

Advanced Technology Laboratories, Inc. believes that Level 10 HDI is substantially equivalent to the currently marketed ATL HDI 3000 diagnostic ultrasound system and Storz Renaissance A/B Scan.

4) Device Description:

Level 10 HDI 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) or in a combination of modes. Level 10 HDI also gives the opertor 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. Level 10 HDI has an output display with two basic indices, a mechanical index and a thermal index, which are both automatically displayed.

The Level 10 HDI 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.

The Level 10 HDI 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.

Level 10 HDI 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:

Level 10 HDI is intended for cardiac, peripheral vascular, fetal imaging and other, and ophthalmic intended uses as defined FDA guidance documents.

Typical examinations using Level 10 HDI 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 operate 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 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 - 4.0	(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.