

AUG 21 1998

K974269

**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:**

Medison America, Inc.  
6616 Owens Drive  
Pleasanton, CA 94588  
Bob Leiker  
Vice President, Regulatory and Quality  
Telephone: (510) 463-1830

Prepared June 24, 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 and Accessories

Proprietary Name:

SonoAce 8800 Diagnostic Ultrasound System and Transducers.  
Also called HDI® 1500 Diagnostic Ultrasound System and Transducers.

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

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

Medison America, Inc believes that SA8800/HDI 1500 Ultrasound system is substantially equivalent to the currently marketed ATL HDI 5000 System, K961459.

**4) Device Description:**

The SA 8800/HDI 1500 scanner 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 SA 8800/HDI 1500 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 SA 8800/HDI 1500 has real time acoustic output display with two basic indices, a mechanical index and a thermal index, which are both automatically displayed.

Eight 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. Patient contact materials are the same as those previously cleared in the predicate device, ATL's HDI 5000 Ultrasound System and Transducers (K961459).

The SA-8800/HDI 1500 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. The same clinical uses were cleared for the predicate device, ATL's 5000 (K961459).

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.

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 SA-8800/HDI 1500 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 SA8800/HDI 1500 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 SA 8800/HDI 1500 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.

5) **Intended Use:**

SonoAce 8800/HDI 1500 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

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.
- 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 <sup>2</sup>
MI	1.9

The limits are the same as predicate Track 3 devices.



AUG 21 1998

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Robert Leiker  
Vice President  
Regulatory and Quality  
Medison America, Inc.  
6616 Owens Drive  
Pleasanton, CA 94588

Re: K974269  
Trade Name: SA8800/HDI 1500 Diagnostic Ultrasound System  
Regulatory Class: II/892.1550/892.1560  
Product Code: 90 IYN/90 IYO  
Dated: July 7, 1998  
Received: July 9, 1998

Dear Mr. Leiker:

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 SA8800/HDI 1500 Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

CS-2, C7-4, C9-5ICT, L7-4,  
L12-5, P4-2, P7-4, D2 CW

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:

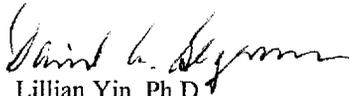
Food and Drug Administration  
Center for Devices and Radiological Health  
Document Mail Center (HFZ-401)  
9200 Corporate Boulevard  
Rockville, Maryland 20850

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 Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

*for* 

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

**Ultrasound Device Indications Statement**

510(k) Number: K974269  
 Device Name: SA 8800 System/HDI 1500 Ultrasound System

Indications for Use: Diagnostic ultrasound imaging or fluid flow analysis 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 (See Note 3)		N	N	N	N	N	N		Note 1	Notes 2, 4, 7, 8
Abdominal		N	N	N	N	N	N		Note 1	Notes 2, 4, 7, 8
Intraoperative: (See Note 6)		N	N	N		N	N		Note 1	Notes 2, 4, 7, 8
Intraoperative Neurological		N	N	N	N	N	N		Note 1	Notes 4, 8
Pediatric		N	N	N	N	N	N		Note 1	Notes 2, 4, 7, 8
Small Organ (See Note 5)		N	N	N		N	N		Note 1	Notes 2, 4, 7, 8
Neonatal Cephalic		N	N	N	N	N	N		Note 1	Notes 4, 8
Adult Cephalic		N	N	N	N	N	N		Note 1	Notes 4, 7, 8
Cardiac		N	N	N	N	N	N		Note 1	Notes 4, 7, 8
Transesophageal										
Transrectal		N	N	N		N	N		Note 1	Note 2, 7, 8
Transvaginal		N	N	N		N	N		Note 1	Note 2, 7, 8
Transurethral										
Intravascular										
Peripheral vascular		N	N	N		N	N		Note 1	Note 4, 8
Laparoscopic										
Musculo-skeletal Conventional		N	N	N		N	N		Note 1	Notes 2, 4, 8
Musculo-skeletal Superficial										
Other (Specify)										

N = new indication; P = All transducers were previously cleared in K961459, Level 10 HDI™ Ultrasound System, all transducers are new to SA 8800/HDI 1500; E = added under Appendix E

Other Indications or Modes:

- Note 1: PWD/Color Doppler, PWD/Power Doppler, CWD/Color Doppler, CWD/Power Doppler.
- Note 2: Includes imaging for guidance of biopsy
- Note 3: Includes infertility monitoring of follicle development
- Note 4: Color M-mode
- Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients.
- Note 6: Abdominal organs and peripheral vessel
- Note 7: Tissue Harmonic Imaging (THI)
- Note 8: 3D Imaging

Concurrence of CDRH, Office of Device Evaluation (ODE)  
Prescription Use (Per 21 CFR 801.109)

Prescription Use   
 (Per 21 CFR 801.109)

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

Basic Information

*David A. Segman*

**Ultrasound Device Indications Statement**

510(k) Number: K974269  
 Device Name: SA 8800 System/HDI 1500 Ultrasound System  
 Transducer: C5-2/5.0-2.0 MHz/40mm/Convex Array

Indications for Use: Diagnostic ultrasound imaging or fluid flow analysis 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 (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
Intraoperative: (Specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (Specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Muscuio-skeletal Superficial										
Other (Specify)										

N = new indication; P = All transducers were previously cleared in K961459, Level 10 HDI™ Ultrasound System, all transducers are new to SA 8800/HDI 1500; E = added under Appendix E

Other Indications or Modes:

Note 1: PWD/Color Doppler, PWD/Power Doppler, CWD/Color Doppler, CWD/Power Doppler.

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D Imaging

Concurrence of CDRH, Office of Device Evaluation (ODE)  
Prescription Use (Per 21 CFR 801.109)

Prescription Use   
 (Per 21 CFR 801.109)

*David C. Segerson*  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal, ENT,  
 and Radiological Devices

Basic Information

510(k) Number K974269

**Ultrasound Device Indications Statement**

510(k) Number: K974269  
 Device Name: SA 8800 System/HDI 1500 Ultrasound System  
 Transducer: C7-4/7.0-4.0 Mhz/40mm/Convex Array

Indications for Use: Diagnostic ultrasound imaging or fluid flow analysis 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 (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
Intraoperative: (Specify)										
Intraoperative Neurological										
Pediatric		P	P	P		P	P		Note 1	Notes 2, 4, 7, 8
Small Organ (Specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (Specify)										

N = new indication; P = All transducers were previously cleared in K961459, Level 10 HDI™ Ultrasound System, all transducers are new to SA 8800/HDI 1500; E = added under Appendix E

Other Indications or Modes:

- Note 1: PWD/Color Doppler, PWD/Power Doppler, CWD/Color Doppler, CWD/Power Doppler.
- Note 2: Includes imaging for guidance of biopsy
- Note 3: Includes infertility monitoring of follicle development
- Note 4: Color M-mode
- Note 7: Tissue Harmonic Imaging (THI)
- Note 8: 3D Imaging

Concurrence of CDRH, Office of Device Evaluation (ODE)  
Prescription Use (Per 21 CFR 801.109)

*David L. Segerson*  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal, ENT,  
 and Radiological Devices  
 510(k) Number K974269

Prescription Use   
 (Per 21 CFR 801.109)

**Ultrasound Device Indications Statement**

510(k) Number: K974269  
 Device Name: SA 8800 System/HDI 1500 Ultrasound System  
 Transducer: C9-5ICT/9.0-5.0 MHz/8mm/Convex Array

Indications for Use: Diagnostic ultrasound imaging or fluid flow analysis 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 (See Note3)		P	P	P		P	P		Note 1	Notes 2, 7, 8
Abdominal										
Intraoperative: (Specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (Specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal		P	P	P		P	P		Note 1	Notes 2, 7, 8
Transvaginal		P	P	P		P	P		Note 1	Notes 2, 7, 8
Transurethral										
Intravascular										
Peripheral vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (Specify)										

N = new indication; P = All transducers were previously cleared in K961459, Level 10 HDI™ Ultrasound System, all transducers are new to SA 8800/HDI 1500; E = added under Appendix E

Other Indications or Modes:

- Note 1: PWD/Color Doppler, PWD/Power Doppler, CWD/Color Doppler, CWD/Power Doppler.
- Note 2: Includes imaging for guidance of biopsy.
- Note 3: Includes infertility monitoring of follicle development
- Note 7: Tissue Harmonic Imaging (THI)
- Note 8: 3D Imaging

Concurrence of CDRH, Office of Device Evaluation (ODE)  
 Prescription Use (Per 21 CFR 801.109)

Prescription Use   
 (Per 21 CFR 801.109)

*David A. Ferguson*  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal, ENT,  
 and Radiological Devices  
 510(k) Number K974269

**Ultrasound Device Indications Statement**

510(k) Number: K974269  
 Device Name: SonoAce 8800 System/HDI 1500 Ultrasound System  
 Transducer: L7-4/7.0-4.0 MHz/38mm/Linear Array

Indications for Use: Diagnostic ultrasound imaging or fluid flow analysis 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		P	P	P		P	P		Note 1	Notes 2, 4, 7, 8
Intraoperative: (Specify)										
Intraoperative Neurological										
Pediatric		P	P	P		P	P		Note 1	Notes 2, 4, 7, 8
Small Organ (See Note 5)		P	P	P		P	P		Note 1	Notes 2, 4, 7, 8
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vascular		P	P	P		P	P		Note 1	Notes 4, 8
Laparoscopic										
Musculo-skeletal Conventional		P	P	P		P	P		Note 1	Notes 2, 4, 8
Musculo-skeletal Superficial										
Other (Specify)										

N = new indication; P = All transducers were previously cleared in K961459, Level 10 HDI™ Ultrasound System, all transducers are new to SA 8800/HDI 1500; E = added under Appendix E

Other Indications or Modes:

Note 1: PWD/Color Doppler, PWD/Power Doppler, CWD/Color Doppler, CWD/Power Doppler.

Note 2: Includes imaging for guidance of biopsy

Note 4: Color M-mode

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

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D Imaging

Concurrence of CDRH, Office of Device Evaluation (ODE)  
 Prescription Use (Per 21 CFR 801.109)

Prescription Use   
 (Per 21 CFR 801.109)

*David A. Beynon*  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal, ENT,  
 and Radiological Devices

Basic Information

510(k) Number K974269

**Ultrasound Device Indications Statement**

510(k) Number: K974269  
 Device Name: SA 8800 System/HDI 1500 Ultrasound System  
 Transducer: L12-5/12.0-5.0 MHz/38mm/Linear Array

Indications for Use: Diagnostic ultrasound imaging or fluid flow analysis 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										
Intraoperative: (See Note 6)		P	P	P		P	P		Note 1	Notes 2, 4, 7, 8
Intraoperative Neurological										
Pediatric		P	P	P		P	P		Note 1	Notes 2, 4, 7, 8
Small Organ (See Note 5)		P	P	P		P	P		Note 1	Notes 2, 4, 7, 8
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vascular		P	P	P		P	P		Note 1	Notes 4, 8
Laparoscopic										
Musculo-skeletal Conventional		P	P	P		P	P		Note 1	Notes 2, 4, 8
Musculo-skeletal Superficial										
Other (Specify)										

N = new indication; P = All transducers were previously cleared in K961459, Level 10 HDI™ Ultrasound System, all transducers are new to SA 8800/HDI 1500; E = added under Appendix E

Other Indications or Modes:

Note 1: PWD/Color Doppler, PWD/Power Doppler, CWD/Color Doppler, CWD/Power Doppler.

Note 2: Includes imaging for guidance of biopsy

Note 4: Color M-mode

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

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D Imaging

Concurrence of CDRH, Office of Device Evaluation (ODE)  
 Prescription Use (Per 21 CFR 801.109)

*David G. Johnson*  
 (Division Sign-Off)

Division of Reproductive, Abdominal, ENT,  
 and Radiological Devices

Prescription Use   
 (Per 21 CFR 801.109)

510(k) Number K974269

**Ultrasound Device Indications Statement**

510(k) Number: K974269  
 Device Name: SA 8800 System/HDI 1500 Ultrasound System  
 Transducer: P4-2/4.0-2.0 MHz/20mm/Phased Array

Indications for Use: Diagnostic ultrasound imaging or fluid flow analysis 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 (See Note 3)		P	P	P	P	P	P		Note 1	Notes 4, 7, 8
Abdominal		P	P	P	P	P	P		Note 1	Notes 4, 7, 8
Intraoperative: (Specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (Specify)										
Neonatal Cephalic										
Adult Cephalic		P	P	P	P	P	P		Note 1	Notes 4, 7, 8
Cardiac		P	P	P	P	P	P		Note 1	Notes 4, 7, 8
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (Specify)										

N = new indication; P = All transducers were previously cleared in K961459, Level 10 HDI™ Ultrasound System, all transducers are new to SA 8800/HDI 1500; E = added under Appendix E

Other Indications or Modes:

- Note 1: PWD/Color Doppler, PWD/Power Doppler, CWD/Color Doppler, CWD/Power Doppler.
- Note 3: Includes infertility monitoring of follicle development
- Note 4: Color M-mode
- Note 7: Tissue Harmonic Imaging (THI)
- Note 8: 3D Imaging

Concurrence of CDRH, Office of Device Evaluation (ODE)  
 Prescription Use (Per 21 CFR 801.109)

*David G. Segerson*  
 (Division Sign-Off)

DIVISION of Reproductive, Abdominal, ENT, and Radiological Devices

Prescription Use   
 (Per 21 CFR 801.109)

**Ultrasound Device Indications Statement**

510(k) Number: K974269  
 Device Name: SA 8800 System/HDI 1500 Ultrasound System  
 Transducer: P7-4/7.0-4.0 MHz/8mm/Phased Array

Indications for Use: Diagnostic ultrasound imaging or fluid flow analysis 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 (See Note 3)		P	P	P	P	P	P		Note 1	Notes 4, 7, 8
Abdominal		P	P	P	P	P	P		Note 1	Notes 4, 7, 8
Intraoperative: (Specify)										
Intraoperative Neurological		P	P	P	P	P	P		Note 1	Notes 4, 8
Pediatric		P	P	P	P	P	P		Note 1	Notes 4, 7, 8
Small Organ (Specify)										
Neonatal Cephalic		P	P	P	P	P	P		Note 1	Notes 4, 8
Adult Cephalic										
Cardiac		P	P	P	P	P	P		Note 1	Notes 4, 7, 8
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (Specify)										

N = new indication; P = All transducers were previously cleared in K961459, Level 10 HDI™ Ultrasound System, all transducers are new to SA 8800/HDI 1500; E = added under Appendix E

Other Indications or Modes:

- Note 1: PWD/Color Doppler, PWD/Power Doppler, CWD/Color Doppler, CWD/Power Doppler.
- Note 3: Includes infertility monitoring of follicle development
- Note 4: Color M-mode
- Note 7: Tissue Harmonic Imaging (THI)
- Note 8: 3D Imaging

Concurrence of CDRH, Office of Device Evaluation (ODE)  
 Prescription Use (Per 21 CFR 801.109)

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 and Radiological Devices  
 510(k) Number K974269

Prescription Use   
 (Per 21 CFR 801.109)

**Ultrasound Device Indications Statement**

510(k) Number: K974269  
 Device Name: SA 8800 System/HDI 1500 Ultrasound System  
 Transducer: D2 CW/2.0 MHz/Static Probe

Indications for Use: Diagnostic ultrasound imaging or fluid flow analysis 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										
Intraoperative: (Specify)										
Intraoperative Neurological										
Pediatric					P					
Small Organ (Specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac					P					
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (Specify)										

N = new indication; P = All transducers were previously cleared in K961459, Level 10 HDI™ Ultrasound System, all transducers are new to SA 8800/HDI 1500; E = added under Appendix E

Concurrence of CDRH, Office of Device Evaluation (ODE)  
 Prescription Use (Per 21 CFR 801.109)

Prescription Use   
 (Per 21 CFR 801.109)

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