SEP 1 2 2001

K012887

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:

Gary J. Allsebrook, Consultant
Regulatory Management Services
16303 Panoramic Way
San Leandro CA 94578-1116
Telephone: 510-276-2648
Facsimile: 510-276-3559
Email: regman1@home.com

Prepared July 6, 2001

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:
SA6000II Diagnostic Ultrasound System and Transducers.

Classification Names:	FR Number	Product Code
Ultrasound Pulsed Echo Imaging System	892.1560	90-IYO
Diagnostic Ultrasound Transducer	892.1570	90-ITX

3) Identification of the predicate or legally marketed device:

Medison America, Inc. believes that SA6000II Ultrasound System is substantially equivalent to the currently marketed SA5500 System (K992761) and SA9900 System (K002185)

4) Device Description:

The SA6000II 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, or as a combination of these modes. SA6000II 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.

Five different models of transducers are available and any two 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. More detailed explanations of these functions and controls are included in the Operator's manual, and in the software/firmware documentation included in this 510(k) Notification. Patient contact materials are the same as those previously cleared in the predicate device, SA5500 Ultrasound System and Transducers (K992761) and SA9900 Ultrasound System and Transducers (K002185).

The SA6000II uses digital beamforming technology. The SA6000II supports a variety of Linear and Curved Linear Array probes for 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 10 MHz. These probes can be applied to a variety of fields such as fetal, abdominal, intra-operative, pediatric, small organ, neonatal cephalic, adult cephalic, cardiac, trans-rectal, trans-vaginal, peripheral-vascular, muscular-skeletal. The same clinical uses were cleared for the predicate device, SA5500 Ultrasound System (K992761) and SA9900 Ultrasound System (K002185).

SA6000II provides high quality images and various measuring functions. It can 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), APD (anteroposterior abdominal diameter), TTD (transverse trunk diameter), GS (gestational sac), etc.

Biopsy guidelines are provided on screen to assist in the collection of tissue samples, using biopsy guide adapters offered as an optional accessory. The operating Modes of SA6000II are B, M, or as a combination of these modes. M-mode uses the sweep display method that has its images flow from the left to the right on the monitor. The SA6000II supports the Cine function (capable of storing up to 64 frames) and real-time zoom function to the region-of-interest. Management of patient history is possible by an image-filing function. High-resolution images are provided by utilizing a technology called digital dynamic receive focusing.

The SA6000II 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 60601-1-2,) European Norm, Collateral Standard: Electromagnetic Compatibility
- Compliant with the European Medical Device Directive Certificate issued by TUV.

5) Intended Use:

SA6000II intended uses as defined FDA guidance documents are:

- Fetal – OB/GYN
- Abdominal
- Pediatric
- Small Organ (breast, thyroid, testicle)
- Neonatal Cephalic
- Adult Cephalic
- Cardiac
- Trans-Rectal
- Trans-Vaginal
- Peripheral-Vascular
- Muscular-Skeletal (Conventional, Superficial)

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.

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 2D and M-mode, Spectral Doppler, Color Doppler, Power Doppler, or 3D images. Transducer patient contact materials are biocompatible.

The device's acoustic output limits are:

All Applications:	
	(Maximum Range)
I_{SPTA}	720 mW/cm2
MI	1.9

The limits are the same as predicate Track 1 devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 12 2001

Medison America, Inc.
% Mr. Mark Job
Program Manager
TUV Product Service, Inc.
1775 Old Highway 8 NW, Suite 104
NEW BRIGHTON MN 55112-1891

Re: K012887
Trade Name: SonoAce SA-6000II Diagnostic Ultrasound System
Regulatory Class: II/21 CFR 892.1560
Product Code: 90 IYO
Dated: August 24, 2001
Received: August 28, 2001

Dear Mr. Job:

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 SonoAce SA-6000II Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

L5-9EC/7.5MHz/Linear Array
L5-9ER/7.5MHz/Linear Array
C2-4ES/3.0MHz/Curved Linear Array
C3-7ED/4.5MHz/Curved Linear Array
EC4-9ES/6.5MHz/Curved 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.

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, 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, International and Consumer 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,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

Diagnostic Ultrasound Indications for Use Form

510(k) Number: K012887
Device Name: SA6000II Ultrasound System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Mode of Operation

Clinical Application	A	B	M	PWD	CWD	Color Doppler*	Power (Amp) Doppler	Color Velocity Imaging	Combined (B-M)	Other (Specify)
Ophthalmic										
Fetal		P	P						P	Notes 3, 5, 6
Abdominal *(See Note 1)*		P	P						P	Notes 3, 5, 6
Intra-Operative *(See Note 4)*		P	P						P	Note 5, 6
Intra-Operative Neurological										
Pediatric		P	P						P	Notes 3, 5, 6
Small Organ *(See Note 2)*		P	P						P	Notes 3, 5, 6
Neonatal Cephalic		P	P						P	Note 5
Adult Cephalic		P1	P1						P1	Note 5
Cardiac		P	P						P	Note 5
Transesophageal										
Trans-Rectal		P	P						P	Notes 3, 5
Trans-Vaginal		P	P						P	Notes 3, 5
Trans-Urethral										
Intra-Vascular										
Peripheral -Vascular		P	P						P	Note 5
Laparoscopic										
Muscular-Skeletal Conventional		P	P						P	Notes 3, 5, 6
Muscular-Skeletal Superficial		P1	P1						P1	Notes 3, 5, 6
Others(Specify)										

N = new indication; P = previously cleared in K992761, SA5500 Ultrasound System, P1 = previously cleared in K002185, SA9900 Ultrasound System ; E = added under Appendix E
Other Indications or Modes
Note 1: Abdominal, Solid organs, aneurysms(P)
Note 2: For example: thyroid, breast, testes (P)
Note 3: Includes imaging for guidance of biopsy (P, P1)
Note 4: Intra-Abdominal Organs(P)
Note 5: 3D Imaging (P, P1)
Note 6: Harmonic Imaging (P1)

Concurrence of CDRH, Office of Device Evaluation(ODE)

Nancy C Brogdon

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K012887

Diagnostic Ultrasound Indications for Use Form

510(k) Number:
Device Name: SA6000II Ultrasound System
Transducer: L5-9EC (Linear Array 7.5MHz/40mm/128elements)

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Mode of Operation

Clinical Application	A	B	M	PWD	CWD	Color Doppler*	Power (Amp) Doppler	Color Velocity Imaging	Combined (B-M)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal *(See Note 1)*		N	N						N	Notes 3, 5
Intra-Operative *(See Note 4)*		N	N						N	Notes 5
Intra-Operative Neurological										
Pediatric		N	N						N	Notes 3, 5
Small Organ *(See Note 2)*		N	N						N	Notes 3, 5
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Trans-Rectal										
Trans-Vaginal										
Trans-Urethral										
Intra-Vascular										
Peripheral -Vascular		N	N						N	Note 5
Laparoscopic										
Muscular-Skeletal Conventional		N	N						N	Notes 3, 5
Muscular-Skeletal Superficial		N	N						N	Notes 3, 5
Others(Specify)										

N = new indication; P = previously cleared in K992761, SonoAce 5500 Ultrasound System ; E = added under Appendix E
Other Indications or Modes
Note 1: Abdominal, Solid organs, aneurysms
Note 2: For example: thyroid, breast, testes
Note 3: Includes imaging for guidance of biopsy
Note 4: Intra-Abdominal Organs
Note 5: 3D Imaging
Note 6: Harmonic Imaging

Concurrence of CDRH, Office of Device Evaluation(ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K012887

Diagnostic Ultrasound Indications for Use Form

510(k) Number:
Device Name: SA6000II Ultrasound System
Transducer: L5-9ER (Linear Array 7.5MHz/50mm/128elements)

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Mode of Operation

Clinical Application	A	B	M	PWD	CWD	Color Doppler*	Power (Amp) Doppler	Color Velocity Imaging	Combined (B-M)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal *(See Note 1)*		N	N						N	Notes 3, 5
Intra-Operative *(See Note 4)*		N	N						N	Notes 5
Intra-Operative Neurological										
Pediatric		N	N						N	Notes 3, 5
Small Organ *(See Note 2)*		N	N						N	Notes 3, 5
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Trans-Rectal										
Trans-Vaginal										
Trans-Urethral										
Intra-Vascular										
Peripheral -Vascular		N	N						N	Note 5
Laparoscopic										
Muscular-Skeletal Conventional		N	N						N	Notes 3, 5
Muscular-Skeletal Superficial		N	N						N	Notes 3, 5
Others(Specify)										

N = new indication; P = previously cleared in K992761, SonoAce 5500 Ultrasound System ; E = added under Appendix E
Other Indications or Modes
Note 1: Abdominal, Solid organs, aneurysms
Note 2: For example: thyroid, breast, testes
Note 3: Includes imaging for guidance of biopsy
Note 4: Intra-Abdominal Organs
Note 5: 3D Imaging
Note 6: Harmonic Imaging

Concurrence of CDRH, Office of Device Evaluation(ODE)

Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K012887

Diagnostic Ultrasound Indications for Use Form

510(k) Number:
Device Name: SA6000II Ultrasound System
Transducer: C2-4ES (Curved Linear Array 3.0MHz/20R/128elements)

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Mode of Operation

Clinical Application	A	B	M	PWD	CWD	Color Doppler*	Power (Amp) Doppler	Color Velocity Imaging	Combined (B-M)	Other (Specify)
Ophthalmic										
Fetal		N	N						N	Note 5
Abdominal *(See Note 1)*		N	N						N	Note 5
Intra-Operative *(See Note 4)*		N	N						N	Note 5
Intra-Operative Neurological										
Pediatric		N	N						N	Note 5
Small Organ *(See Note 2)*		N	N						N	Note 5
Neonatal Cephalic		N	N						N	Note 5
Adult Cephalic		N	N						N	Note 5
Cardiac		N	N						N	Note 5
Transesophageal										
Trans-Rectal										
Trans-Vaginal										
Trans-Urethral										
Intra-Vascular										
Peripheral -Vascular		N	N						N	Note 5
Laparoscopic										
Muscular-Skeletal Conventional										
Muscular-Skeletal Superficial										
Others(Specify)										

N = new indication; P = previously cleared in K992761, SonoAce 5500 Ultrasound System ; E = added under Appendix E
Other Indications or Modes
Note 1: Abdominal, Solid organs, aneurysms
Note 2: For example: thyroid, breast, testes
Note 3: Includes imaging for guidance of biopsy
Note 4: Intra-Abdominal Organs
Note 5: 3D Imaging
Note 6: Harmonic Imaging

Concurrence of CDRH, Office of Device Evaluation(ODE)

Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K012887

Diagnostic Ultrasound Indications for Use Form

510(k) Number:
Device Name: SA6000II Ultrasound System
Transducer: C3-7ED (Curved Linear Array 4.5MHz/50R/128elements)

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Mode of Operation

Clinical Application	A	B	M	PWD	CWD	Color Doppler*	Power (Amp) Doppler	Color Velocity Imaging	Combined (B-M)	Other (Specify)
Ophthalmic										
Fetal		N	N						N	Notes 3, 5, 6
Abdominal *(See Note 1)*		N	N						N	Notes 3, 5, 6
Intra-Operative *(See Note 4)*		N	N						N	Notes 5, 6
Intra-Operative Neurological										
Pediatric		N	N						N	Notes 3, 5, 6
Small Organ *(See Note 2)*		N	N						N	Notes 3, 5, 6
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Trans-Rectal										
Trans-Vaginal										
Trans-Urethral										
Intra-Vascular										
Peripheral -Vascular										
Laparoscopic										
Muscular-Skeletal Conventional		N	N						N	Notes 3, 5, 6
Muscular-Skeletal Superficial		N	N						N	Notes 3, 5, 6
Others(Specify)										

N = new indication; P = previously cleared in K992761, SonoAce 5500 Ultrasound System ; E = added under Appendix E
Other Indications or Modes
Note 1: Abdominal, Solid organs, aneurysms
Note 2: For example: thyroid, breast, testes
Note 3: Includes imaging for guidance of biopsy
Note 4: Intra-Abdominal Organs
Note 5: 3D Imaging
Note 6: Harmonic Imaging

Concurrence of CDRH, Office of Device Evaluation(ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K012887

Diagnostic Ultrasound Indications for Use Form

510(k) Number:
Device Name: SA6000II Ultrasound System
Transducer: EC4-9ES (Curved Linear Array 6.5MHz/10R/128elements)

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Mode of Operation

Clinical Application	A	B	M	PWD	CWD	Color Doppler*	Power (Amp) Doppler	Color Velocity Imaging	Combined (B-M)	Other (Specify)
Ophthalmic										
Fetal		N	N						N	Notes 3, 5
Abdominal *(See Note 1)*		N	N						N	Notes 3, 5
Intra-Operative *(See Note 4)*		N	N						N	Notes 5
Intra-Operative Neurological										
Pediatric		N	N						N	Notes 3, 5
Small Organ *(See Note 2)*		N	N						N	Notes 3, 5
Neonatal Cephalic		N	N						N	Notes 5
Adult Cephalic										
Cardiac										
Transesophageal										
Trans-Rectal		N	N						N	Notes 3, 5
Trans-Vaginal		N	N						N	Notes 3, 5
Trans-Urethral										
Intra-Vascular										
Peripheral -Vascular		N	N						N	Notes 3, 5
Laparoscopic										
Muscular-Skeletal Conventional		N	N						N	Notes 3, 5
Muscular-Skeletal Superficial		N	N						N	Notes 3, 5
Others(Specify)										

N = new indication; P = previously cleared in K992761, SonoAce 5500 Ultrasound System; E = added under Appendix E
Other Indications or Modes
Note 1: Abdominal, Solid organs, aneurysms
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