JUL - 8 1999

510(k) SUMMARY

K992155

MODEL S-VNW 5-10 VOLUSON® SMALL PARTS TRANSDUCER
MODEL S-VAW 4-7 VOLUSON® ABDOMINAL TRANSDUCER

1. **COMPANY INFORMATION.** *Name:* Medison America, Inc. *Address:* 6616 Owens Drive, Pleasanton, CA 94588. *Phone:* (925) 463-1830. *Contact:* Bob Leiker - Vice President, Regulatory and Quality. *Manufacturer:* Kretztechnik AG, Tiefenbach 15, A-4871, Zipf, Austria.

2. **DEVICE IDENTIFICATION.** *Trade Name:* (1) Model S-VNW 5-10 Voluson® Small Parts Transducer (2) Model S-VAW 4-7 Voluson® Abdominal Transducer. *Common Name:* Diagnostic Ultrasound Transducer. *Classification Name:* Diagnostic Ultrasound Transducer, 90-ITX.

3. **PREDICATE DEVICE.** *For Model S-VNW 5-10:* Kretztechnik Transducer Model S-NLM 5-10. *For Model S-VAW 4-7:* Kretztechnik Transducer Models S-VSW 3-5 and S-ACA 4-7. The three predicate devices were all cleared with the Combison 530D system under 510(k)'s K940942 and K974813. See also Combison 530D Special Report dated October 23, 1997.

4. **DEVICE DESCRIPTION.** *General:* Transducer S-VNW 5-10 is a multielement, mechanically steered linear array (volume) probe for use with the Combison 530D Diagnostic Ultrasound System. The center frequency is 7.5 MHz, and the nominal transmit frequency range is 5 to 10 MHz. The scan width is 40 mm and the maximum depth range is 75 mm. Transducer S-VAW 4-7 is a multielement curved array probe for use with the Combison 530D system. The center frequency is 4.5 MHz, and the nominal transmit frequency range is 4 to 7 MHz. The image starting width is approximately 70 mm and the maximum depth range is 200 mm. *Operating Modes:* Both Transducer S-VNW 5-10 and Transducer S-VAW 4-7 operate in B-mode (including three-dimensional volume imaging), M-mode, Pulsed Doppler, and Color Flow modes.

5. **INTENDED USES.** *Transducer S-VNW 5-10:* Pediatric; small organs (including thyroid, testicles, salivary gland, breast, and lymph nodes); peripheral vascular; and musculoskeletal-conventional. *Transducer S-VAW 4-7:* Fetal, abdominal, pediatrics, and small organs.

6. **COMPARISON WITH PREDICATE DEVICE.** *Transducer S-VNW 5-10:* This device is a modification of its predicate device. The major difference is that the modified transducer contains 192 elements while the predicate device has 128. *Trans*ducer S-VAW 4-7: This device is a combination of its two predicate devices. The principle difference is that the subject device is a curved array while one of the two predicate devices was an annular array. *Evaluation:* Transducers S-VNW 5-10 and S-VAW 4-7 are both similar in design and function to their respective predicate devices. Neither transducer introduces new modes of operation or indications for use beyond those previously cleared.

7. **PERFORMANCE DATA.** Measurement accuracy, precision of volume reconstruction, electrical and thermal safety, and software performance have been tested in accordance with applicable guidelines and standards with satisfactory results. Patient contact materials remain unchanged. Acoustic output has been measured as specified in pertinent FDA recognized standards and is reported according to Track 3.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 8 1999

Medison America, Inc.
C/O Carole Stamp
TUV product Services
1775 Old Highway 8
New Brighton, MN 55112-1891

RE: K992155
Model S-VNW 5-10 Voluson Small parts Transducer
Model S-VAW 4-7 Voluson Abdominal Transducer
Dated: June 24, 1999
Received: June 25, 1999
Regulatory Class: II
21 CFR 892.1570/Procode: 90 ITX

Dear Ms. Stamp:

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 Combison 530D Diagnostic Ultrasound System as described in your premarket notification:

Transducer Model Number(s):

Model S-VNW 5-10 Voluson Small Parts
Model S-VAW 4-7 Voluson Abdominal

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:

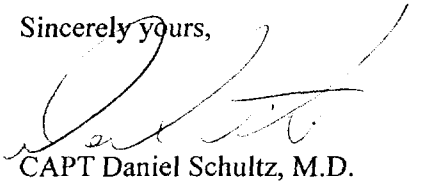
Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

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 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 Robert Phillips, Ph.D at (301) 594-1212.

Sincerely yours,



CAPT Daniel Schultz, M.D.
Acting 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:
Device Name: Voluson C530D Ultrasound System
Transducer: **S-VNW 5-10 Small Part Volume Transducer**

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 (Amplitude) Doppler *	Color Velocity Imaging	Combined (Specify)* See Note 1	Other (Specify) See Note 2
Ophthalmic										
Fetal										
Abdominal										
Intraoperative: (Specify)										
Intraoperative Neurological										
Pediatric		E	E	E		E	E		E	N
Small Organ (Specify) See Note 3		E	E	E		E	E		E	N
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vascular		E	E	E		E	E		E	N
Laparoscopic										
Musculo-skeletal Conventional		E	E	E		E	E		E	N
Musculo-skeletal Superficial										
Other (Specify)										

N = new indication; P = Previously cleared in K940942, Voluson C530D Ultrasound System; P^1 = Previously cleared in K974813, Voluson C530D Ultrasound System with Power Doppler; E = added under Appendix E

Other Indications or Modes:
Note 1: PWD/Color Doppler, PWD/Power Doppler.
Note 2: 3D Volume Imaging Mode
Note 3: For example: thyroid, testicles, salivary gland, breast, lymph nodes, and pediatric patients.

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

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K992155

Prescription Use ✓
(Per 21 CFR 801.109)

Ultrasound Device Indications Statement

510(k) Number:
Device Name: Voluson C530D Ultrasound System
Transducer: **S-VAW 4-7 Abdominal Volume Transducer**

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 (Amplitude) Doppler *	Color Velocity Imaging	Combined (Specify)* See Note 1	Other (Specify) See Note 2
Ophthalmic										
Fetal		P	P	P		P	P^1			P
Abdominal		P	P	P		P	P^1			P
Intraoperative: (Specify)										
Intraoperative Neurological										
Pediatric		P	P	P		P				P
Small Organ (Specify) See Note 3		P	P	P		P				P
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 = Previously cleared in K940942, Voluson C530D Ultrasound System; P^1 = Previously cleared in K974813, Voluson C530D Ultrasound System with Power Doppler; E = added under Appendix E

Other Indications or Modes:
Note 1: PWD/Color Doppler, PWD/Power Doppler.
Note 2: 3D Volume Imaging Mode
Note 3: For example: thyroid, testicles, salivary gland, breast, lymph nodes, and pediatric patients.

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