K984639 (3 pages)

JUL 12 1999

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: (925) 463-1830

Prepared December 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:
S-VNA 5-8 and S-VNA 5-8(B) Ultrasound Transducers.
Also called the Voluson Neonatal Ultrasound Transducers.

Classification Names:	FR Number	Product Code
Diagnostic Ultrasound Transducer	892.1570	90-ITX

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

Medison America, Inc believes that S-VNA 5-8 and S-VNA 5-8(B) Ultrasound Transducers are substantially equivalent to the currently marketed C530D S-VDW 5-8 Transducer, K974813,

and the Medison SA8800/ATL HDI 1500 P7-4 Transducer, K974269.

4) **General Ultrasound Scanner Device Description**

The Voluson C530D scanner (K940942) 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, Pulsed (PW) Doppler and Power Angio Doppler (K974813), or as a combination of these modes. The Voluson C530D 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 Voluson C530D has real time acoustic output display with two basic indices, a mechanical index and a thermal index, which are both automatically displayed.

5) **Transducer S-VNA 5-8(B) Device Description**

The S-VNA 5-8(B) transducer is a mechanically steered curved array (Volume) probe. This is identical to the previously cleared (K940942) endocavitary S-VDW 5-8 probe, with the same materials, same acoustic module, and the same technical and acoustical performance. The primary mechanical difference with the endocavity S-VDW 5-8 probe is the modified (shorter) shaft, designed to allow use on the outer surface of the body.

The VOLUSON® Neonatal transducer S-VNA5-8(B) is an electronic wideband sector-transducer with a center frequency of 6.5 MHz and with switchable scan angles. The direction of insonation is forward in relation to the transducer's longitudinal axis. This device is a hand-held, 128 element, curved linear array probe. In addition to B-Mode and M-Mode, this probe can be operated in steerable pulsed Doppler, Color Doppler, Color Power Angio Doppler, and 3D Imaging. Similar to the S-VDW 5-8 transducer, the S-VN A5-8(B) also allows the performance of a 3D volume scan by internally sweeping the array in a lateral direction, automatically upon a key press. The images thus obtained from sectional planes perpendicular to each other can be displayed synoptically on the screen. This device is intended for use with the Combison/Voluson C530D Diagnostic Ultrasound Scanner for transcutaneous imaging as an aid in the detection and assessment of physical and functional abnormalities using established diagnostic criteria. The patient contact materials for biological evaluation that are brought into contact with patients are exactly the same as those of the previously cleared Combison/Voluson C530D Diagnostic Ultrasound System and Transducers (K940942/K974813), specifically the S-VDW 5-8 Endocavity transducer.

The S-VNA 5-8(B) Ultrasound Transducer 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:

The S-VNA 5-8(B) Ultrasound Transducer intended uses as defined FDA guidance documents are:

- Neonatal Cephalic
- Fetal
- Pediatric and Neonatal Abdominal

Typical examinations performed using this transducer are:

- General abdominal studies including organ surveys, assessment, and retro-peritoneal cavity studies.
- Pediatric scans of organs and bony structures.
- Neonatal head studies.
- Biopsy guidance for tissue or fluid sampling.

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, Spectral Doppler, Color Doppler, Power Doppler, and 3D images. Scanhead 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 3 devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 12 1999

Mr. Bob Leiker
Vice President, Regulatory and Quality Assurance
Medison America, Inc.
6616 Owens Drive
Pleasanton, California 94588

Re: K984639
Trade Name: S-VNA 5-8 (B) Diagnostic Ultrasound Transducer
Regulatory Class: II
21CFR 892.1570/Procode: 90 ITX
Dated: June 4, 1999
Received: June 8, 1999

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 transducer intended for use with the Voluson C530D Ultrasound System, as described in your premarket notification:

Transducer Model Number

S-VNA 5-8 (B) Diagnostic Ultrasound Transducer

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 Paul M. Gammell, Ph.D. at (301) 594-1212.

Sincerely yours,

CAPT Daniel G. 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

Enclosure(s)

Ultrasound Device Indications Statement

510(k) Number: K984639
Device Name: Voluson C530D Ultrasound System
Summary of previously cleared, and new Indications for Use

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 (3D Imaging) See Note 2
Ophthalmic										
Fetal		P	P	P		P	P^1		P	P
Abdominal		P	P	P		P	P^1		P	P
Intraoperative: (Specify)										
Intraoperative Neurological										
Pediatric		P	P	P		P	P^1		P	P
Small Organ (Specify) See Note 3		P	P	P		P	P^1		P	P
Neonatal Cephalic – See Note 4		N	N	N		N	N		N	N
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal		P	P	P		P	P^1		P	P
Transvaginal		P	P	P		P	P^1		P	P
Transurethral										
Intravascular										
Peripheral vascular		P	P	P		P	P^1		P	P
Laparoscopic										
Musculo-skeletal Conventional		P	P	P		P	P^1		P	P
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.
Note 4: Transfontanell diagnostics of neonates.

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 K984639

Ultrasound Device Indications Statement

510(k) Number: K984639
Device Name: Voluson C530D Ultrasound System
Transducer: S-VNA 5-8(B) 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 (3D Imaging) See Note 2
Ophthalmic										
Fetal										
Abdominal		N	N	N		N	N		N	N
Intraoperative: (Specify)										
Intraoperative Neurological										
Pediatric		N	N	N		N	N		N	N
Small Organ (Specify)										
Neonatal Cephalic – See Note 4		N	N	N		N	N		N	N
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' = 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 4: Transfontanell diagnostics of neonates.

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 K984639

Prescription Use _____
(Per 21 CFR 801.109)