K993517

NOV - 2 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
Gary J. Allsebrook
Regulatory Affairs
Telephone: (925) 463-1830
Prepared September 8, 1999

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:
Combison ® 530/Voluson® 530D Diagnostic Ultrasound System,
Tissue Harmonic Imaging (THI-Mode) Option.

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 Combison® 530/Voluson® 530D Tissue Harmonic Imaging (THI-Mode) Option is substantially equivalent to the same feature introduced in the Medison, SA8800/HDI 1500 System (K974269).

4) **Device Description:**

Combison® 530/Voluson 530D:

The Combison® 530/Voluson® 530D scanner is a multiple-mode, multiple-application ultrasound imaging system. The cart-mounted console contains an ultrasound generator/receiver offering a full complement of conventional operating modes, software-based parameter controls, and recording. The selection of twelve transducers offered with the system permits a wide range of clinical applications. 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 were tested for biocompatibility in accordance with their intended use and are used for each individual transducer.

The Combison® 530/Voluson® 530D uses digital beamforming technology. The Combison® 530/Voluson® 530D supports a variety of linear and convex 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 3.5 MHz to 7.5 MHz. The Combison® 530/Voluson® 530D provides high quality

images and various measuring functions. Biopsy guidelines are provided on screen to assist in the collection of tissue samples, using biopsy guide adapters offered as an optional accessory. Operating Modes of the Combison® 530/Voluson® 530D are B, B/B, B/M, M and, Doppler, Volume and Power Doppler Mode. 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 clinical uses were previously cleared for the Combison® 530/Voluson® 530D, K940942, K974813 and K992155 respectively.

Please note that the scanner and probes are not the subject of this submission as they are all covered under various 510(k) submissions and/or letters to file where applicable. The above information is provided for informative purposes. The following is the subject of this 510(k) submission:

Tissue Harmonic Imaging (THI-Mode) Option: Tissue Harmonic Imaging (THI) is a B-Mode imaging technique that enables a dramatic reduction in naturally occurring artifacts caused by interaction of certain tissue types and low frequency soundwaves. Seven of the twelve probes offered with the system will be indicated for Tissue Harmonic Imaging (THI-Mode). The THI-Mode will be used for fetal, abdominal, pediatric, and small organ clinical applications. The THI-Mode was previously cleared for use on the SA 8800/HDI 1500 system in K974269. The actual option consists of a software add-on.

5) **Intended Use(s):**

- Fetal - OB/GYN
- Abdominal
- Small Organs (breast, thyroid, testicle)
- Pediatric
- Neonatal Cephalic

- Trans-Vaginal
- Trans-Rectal
- Peripheral Vascular

Typical examinations performed using the system are:

- General abdominal and pelvic studies including organ surveys, assessment, and retroperitoneal cavity studies.
- Study of small parts and superficial structures including breasts, shoulders, thyroid, and the abdominal wall.
- Pediatric scans of organs, superficial, and bony structures.
- Monitoring procedures for infertility studies (other than in vitro fertilization).
- First, second and third trimester pregnancy studies.
- Neonatal head studies.
- Podiatry scans of superficial structures including muscles, tendons and bones.
- Prostate, bladder and rectum visualization.

5) 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. Scanhead patient contact materials are biocompatible.

The device's acoustic output limits are:

All Applications:

TIS/TIB/TIC	0.0 – 4.0	Range
$I_{SPTA.3}$	720mW/cm^2	Maximum
MI	1.9	Maximum

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

NOV - 2 1999

Medison America, Inc.
c/o Carole Stamp
510(k) Program Manager
TUV Product Service
1775 Old Highway 8
New Brighton, MN 55112-1891

Re: K993517
Combison530/Voluson 530D Diagnostic System with
Tissue Harmonic Imaging
Dated: October 15, 1999
Received: October 18, 1999
Regulatory class: II
21 CFR 892.1560/Procode: 90 IYO
21 CFR 892.1550/Procode: 90 IYN
21 CFR 892.1570/Procode: 90 ITX

Dear Mr. Carole:

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 Combison530/Voluson 530D Ultrasound System with Tissue Harmonic Imaging, as described in your premarket notification:

Transducer Model Number

S-AB 2-5 Abdominal Curved Array
S-ACP 3-5 Abdominal Curved Array
S-ACP 4-7 Abdominal Curved Array
S-NLP 5-10 Small Parts Linear Array
S-VAW 3-5 Abdominal Volume
S-VAW 4-7 Abdominal Volume
S-VNW 5-10 Small Parts Volume

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

Sincerely yours,

for David G. Schultz

CAPT. Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4.3. Indications for Use

510(k) Number: K940942 and K974813
Device Name: Combison 530D Ultrasound System
Summary of previously cleared Indications for Use

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

Clinical Application	Mode of Operation (*includes simultaneous B-mode)									
	A	B	M*	PWD*	CWD*	Color Doppler*	Power (Amplitude) Doppler*	Color Velocity Imaging	Combined (Specify)*	Other (Specify)
Ophthalmic										
Fetal		P	P	P		P	P^1		Note 1	Notes 2,3,5
Abdominal		P	P	P		P	P^1		Note 1	Notes 2,3,5
Intra-Operative (Specify)										
Intraoperative Neurological										
Pediatric		P	P	P		P	P^1		Note 1	Notes 2,3,5
Small Organ (Specify)See Note4		P	P	P		P	P^1		Note 1	Notes 2,3,5
Neonatal Cephalic		P	P	P		P	P^1		Note 1	Note 2
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal		P	P	P		P	P^1		Note 1	Notes 2,3
Transvaginal		P	P	P		P	P^1		Note 1	Notes 2,3
Transurethral										
Intravascular										
Peripheral Vascular		P	P	P		P	P^1		Note 1	Notes 2,3,5
Laparascopic										
Muscular-Skeletal Conventional		P	P	P		P	P^1		Note 1	Notes 2,3,5
Muscular-Skeletal Superficial										
Others (Specify)										

N = new indication; P = previously cleared in K940942 Combison 530D Ultrasound System,
P^1 = previously cleared in K974813 Combison 530D System with Power Doppler, E= added under Appendix E

Other Indications or Modes:
Note 1: PWD/Color Doppler, PWD/Power Doppler (P)
Note 2: 3D Volume Imaging Mode (P)
Note 3: Includes imaging for guidance of biopsy (P)
Note 4: For example: thyroid, testicles, salivary gland, breast, lymph nodes and pediatric patients (P)
Note 5: Tissue Harmonic Imaging (N)

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 K993517

510(K) Number:
Device Name: Combison 530D Ultrasound System
Transducer: **S-AB 2-5 Abdominal Curved Array Transducer**

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

Clinical Application	Mode of Operation (*includes simultaneous B-mode)									
	A	B	M*	PWD*	CWD*	Color Doppler*	Power (Amplitude) Doppler*	Color Velocity Imaging	Combined (Specify)*	Other (Specify)
Ophthalmic										
Fetal		E	E	E		E	E		Note 1	Notes 3,5
Abdominal		E	E	E		E	E		Note 1	Notes 3,5
Intra-Operative (Specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (Specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparascopic										
Muscular-Skeletal Conventional										
Muscular-Skeletal Superficial										
Others (Specify)										

N = new indication; P = previously cleared in K940942 Combison 530D Ultrasound System,
P^1 =previously cleared in K974813 Combison 530D System with Power Doppler, E=added under Appendix E

Other Indications or Modes:
Note 1: PWD/Color Doppler, PWD/ Power Doppler (E)
Note 3: Includes imaging for guidance of biopsy (E)
Note 5: Tissue Harmonic Imaging (N)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

David A. Lyon
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K993517

510(K) Number:
Device Name: Combison 530D Ultrasound System
Transducer: **S-ACP 3-5 Abdominal Curved Array Transducer**

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

Clinical Application	Mode of Operation (*includes simultaneous B-mode)									
	A	B	M*	PWD*	CWD*	Color Doppler*	Power (Amplitude) Doppler*	Color Velocity Imaging	Combined (Specify)*	Other (Specify)
Ophthalmic										
Fetal		E	E	E		E	P[1]		Note 1	Notes 3,5
Abdominal		E	E	E		E	P[1]		Note 1	Notes 3,5
Intra-Operative (Specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (Specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparascopic										
Muscular-Skeletal Conventional										
Muscular-Skeletal Superficial										
Others (Specify)										

N = new indication; P = previously cleared in K940942 Combison 530D Ultrasound System,
P[1] =previously cleared in K974813 Combison 530D System with Power Doppler, E=added under Appendix E

Other Indications or Modes:
Note 1: PWD/Color Doppler, PWD/ Power Doppler (E)
Note 3: Includes imaging for guidance of biopsy (E)
Note 5: Tissue Harmonic Imaging (N)

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 K993517

510(K) Number:
Device Name: Combison 530D Ultrasound System
Transducer: **S-ACP 4-7 Abdominal Curved Array Transducer**

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

Clinical Application	Mode of Operation (*includes simultaneous B-mode)									
	A	B	M*	PWD*	CWD*	Color Doppler*	Power (Amplitude) Doppler*	Color Velocity Imaging	Combined (Specify)*	Other (Specify)
Ophthalmic										
Fetal		E	E	E		E	E		Note 1	Notes 3,5
Abdominal		E	E	E		E	E		Note 1	Notes 3,5
Intra-Operative (Specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (Specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparascopic										
Muscular-Skeletal Conventional										
Muscular-Skeletal Superficial										
Others (Specify)										

N = new indication; P = previously cleared in K940942 Combison 530D Ultrasound System,
P^1 =previously cleared in K974813 Combison 530D System with Power Doppler, E=added under Appendix E

Other Indications or Modes:
Note 1: PWD/Color Doppler, PWD/ Power Doppler (E)
Note 3: Includes imaging for guidance of biopsy (E)
Note 5: Tissue Harmonic Imaging (N)

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 K993517

510(K) Number:
Device Name: Combison 530D Ultrasound System
Transducer: **S-NLP 5-10 Small Part Linear Array Transducer**

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

Clinical Application	Mode of Operation (*includes simultaneous B-mode)									
	A	B	M*	PWD*	CWD*	Color Doppler*	Power (Amplitude) Doppler*	Color Velocity Imaging	Combined (Specify)*	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intra-Operative (Specify)										
Intraoperative Neurological										
Pediatric		E	E	E		E	P^1		Note 1	Notes 3,5
Small Organ (Specify)See Note4		E	E	E		E	P^1		Note 1	Notes 3,5
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		E	E	E		E	P^1		Note 1	Notes 3,5
Laparascopic										
Muscular-Skeletal Conventional		E	E	E		E	P^1		Note 1	Notes 3,5
Muscular-Skeletal Superficial										
Others (Specify)										

N = new indication; P = previously cleared in K940942 Combison 530D Ultrasound System,
P^1 =previously cleared in K974813 Combison 530D System with Power Doppler, E=added under Appendix E

Other Indications or Modes:
Note 1: PWD/Color Doppler, PWD/ Power Doppler (E)
Note 3: Includes imaging for guidance of biopsy (E)
Note 4: For example: thyroid,testicles, salivary gland, breast, lymph nodes and pediatric patients
Note 5: Tissue Harmonic Imaging (N)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

David A. Segraves
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K993517

510(K) Number:
Device Name: Combison 530D Ultrasound System
Transducer: **S-VAW 3-5 Abdominal Volume Transducer**

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

Clinical Application	Mode of Operation (*includes simultaneous B-mode)									
	A	B	M*	PWD*	CWD*	Color Doppler*	Power (Amplitude) Doppler*	Color Velocity Imaging	Combined (Specify)*	Other (Specify)
Ophthalmic										
Fetal		E	E	E		E	E		Note 1	Notes 2,3,5
Abdominal		E	E	E		E	E		Note 1	Notes 2,3,5
Intra-Operative (Specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (Specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparascopic										
Muscular-Skeletal Conventional										
Muscular-Skeletal Superficial										
Others (Specify)										

N = new indication; P = previously cleared in K940942 Combison 530D Ultrasound System,
P^1 =previously cleared in K974813 Combison 530D System with Power Doppler, E=added under Appendix E

Other Indications or Modes:
Note 1: PWD/Color Doppler, PWD/ Power Doppler (E)
Note 2: 3D Volume Imaging Mode (E)
Note 3: Includes imaging for guidance of biopsy (E)
Note 5: Tissue Harmonic Imaging (N)

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 K993517

510(K) Number:
Device Name: Combison 530D 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:

Clinical Application	Mode of Operation (* includes simultaneous B-mode)									
	A	B	M*	PWD*	CWD*	Color Doppler*	Power (Amplitude) Doppler*	Color Velocity Imaging	Combined (Specify)*	Other (Specify)
Ophthalmic										
Fetal		P	P	P		P	P		Note 1	Notes 2,3,5
Abdominal		P	P	P		P	P		Note 1	Notes 2,3,5
Intra-Operative (Specify)										
Intraoperative Neurological										
Pediatric		P	P	P		P	P		Note 1	Notes 2,3,5
Small Organ (Specify)See Note4		P	P	P		P	P		Note 1	Notes 2,3,5
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparascopic										
Muscular-Skeletal Conventional										
Muscular-Skeletal Superficial										
Others (Specify)										

N = new indication; P = previously cleared in K992155 with Combison 530D Ultrasound System, P^1 = previously cleared in K974813 Combison 530D System with power Doppler, E= added under Appendix E

Other Indications or Modes:
Note 1: PWD/Color Doppler, PWD/Power Doppler (P)
Note 2: 3D Volume Imaging Mode (P)
Note 3: Includes imaging for guidance of biopsy (P)
Note 4: For example: thyroid testicles, salivary gland, breast, lymph nodes and pediatric patient
Note 5: Tissue Harmonic Imaging (N)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

David A. Seymour
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K993517

510(K) Number:
Device Name: Combison 530D 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:

Clinical Application	Mode of Operation (* includes simultaneous B-mode)									
	A	B	M*	PWD*	CWD*	Color Doppler*	Power (Amplitude) Doppler*	Color Velocity Imaging	Combined (Specify)*	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intra-Operative (Specify)										
Intraoperative Neurological										
Pediatric		P	P	P		P	P		Note 1	Notes 2,3,5
Small Organ (Specify)See Note3		P	P	P		P	P		Note 1	Notes 2,3,5
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		P	P	P		P	P		Note 1	Notes 2,3,5
Laparascopic										
Muscular-Skeletal Conventional		P	P	P		P	P		Note 1	Notes 2,3,5
Muscular-Skeletal Superficial										
Others (Specify)										

N = new indication; P = previously cleared in K992155 with Combison 530D Ultrasound System,
P^1 = previously cleared in K974813 Combison 530D System with power Doppler, E= added under Appendix E

Other Indications or Modes:
Note 1: PWD/Color Doppler, PWD/Power Doppler (P)
Note 2: 3D Volume Imaging Mode (P)
Note 3: Includes imaging for guidance of biopsy (P)
Note 4: For example: thyroid testicles, salivary gland, breast, lymph nodes and pediatric patient
Note 5: Tissue Harmonic Imaging (N)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

David A. Lepan
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K993517