

SEP 29 1998

Premarket Notification [510(k)] Summary

K974813

Date: December 15, 1997

Trade Name: Combison 530D Power Doppler Mode

510(k) Number:

Common Name: Diagnostic Ultrasound System and Transducers

Classification Name: Ultrasonic Pulsed Echo Imaging System – 90 IYO
Ultrasonic Pulsed Doppler Imaging System – 90 IYN
Diagnostic Ultrasonic Transducer – 90 ITX
(per 21 CFR sections 892.1550, 892.1560 and 892.1570)

Manufacturer's Name: Medison Co., Ltd.

Address: Hasung Building
689-3 Yeoksam-dong,
Kangnam-ku
Seoul, Korea

Corresponding Official: Bob Leiker
Medison America, Inc.
6616 Owens Drive
Pleasanton, CA 94588

Title: Vice President, Regulatory Affairs and Quality Assurance
Telephone: (510) 463-1830
Fax: (510) 463-2646

Predicate: Toshiba SSA380
Predicate 510(k) Number: K933743

Device Description: See Attached

Intended Use: Display of slow blood flows by displaying the Doppler backscatter amplitude of the fluid.

Device Description: The Power Doppler (a.k.a. Angio Doppler) is a new feature of a previously cleared Combison 530D Diagnostic Ultrasound scanner. The Power Doppler is an enhanced Doppler data processing feature that uses previously cleared Color Doppler hardware, but displays only a color encoded signal corresponding to the amplitude of the Doppler signal. It enables visualization of slow blood flows. The data received by the doppler is processed the same way as that for the color Doppler mode. The Power Doppler is used with previously cleared electronic probes.

Track 3 Summary Table:

Track 3 Summary Table below shows each transducer / mode combination, and whether the global maximum displayed MI or TI index is greater than 1.0 for that combination. This table also indicates which modes or mode combination for which acoustic output was reported.

OPERATING MODE	TRANSDUCER MODEL				
	S-PLM5-10	S-ACA4-7	S-ACM3-5	S-NLM5-10	S-VDW5-8
B-mode		✓	✓		
M-mode					
Pulsed Doppler	✓	✓	✓	✓	✓
CW Doppler					
Color Doppler		✓	✓		
Combined(specify)					
Amplitude Doppler	✓ ¹	✓ ¹	✓ ¹		

Indicated with a "✓" is the transducer/mode combination for which the MI or TI is greater than 1.0. Measurements were made on production model transducers. For each transducer/mode combination marked with a "✓¹", acoustic output table is included in a TRACK 3 section of this submission.

Technological Characteristics:

Predicate Device Comparison

	Toshiba SSA380	Voluson 530 D, Power Doppler
K-file #	933743	
Name of product feature	Color Angio Mode evoked by Key labeled ANGIO	Angio Color Imaging, Angio Mode evoked by key labeled ANGIO
Specification	Slow flow: min 1cm/sec	Slow flow: 1 to 8 cm/sec
Claims	Color encoded display of slow blood flows	Color encoded display of slow blood flows
Signal to be displayed	Mean power of Doppler backscatter	Mean power of Doppler backscatter
Colors used for representation	From low to higher amplitudes dark rusty -light rusty -yellow	From low to higher amplitudes Enhance 1 dark blue -light blue -yellow Enhance 2,4 dark red -light red -yellow Enhance 3 dark rusty -light rusty -yellow
Wall motion filter	Digital	Digital
Way of processing mean value of mean P(ower) $P = \sqrt{p^2}$	Digital Correlator Correlator output: P	Digital Correlator Correlator output :P ² , P is calculated in the Log compressor
Bits used for P-signal display	5	8
Filter for inline signals	Moving Average Filter	Inline filter



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

SEP 29 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K974813
Combison 530D Diagnostic Ultrasound Scanner with Power Doppler
Regulatory Class: II/21 CFR 892.1550
Product Code: 90 IYN
Dated: August 26, 1998
Received: August 28, 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 Combison 530D Diagnostic Ultrasound Scanner with Power Doppler Mode, as described in your premarket notification:

Transducer Model Number

S-ACA4-7 S-PLM5-10 S-ICA5-8
S-ACM3-5 S-VDW5-8 S-NLP5-10
S-NLM5-10 S-ACP3-5

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>".

Page 3 - Bob Leiker

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

for David G. Seymour

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

Combison 530D with Probe: S-ACA4-7

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

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P	P		P	N			
Abdominal		P	P	P		P	N			
Intra-Operative (Specify)										
Intra-Operative Neurological										
Pediatric										
Small Organ (Specify)*										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Muscular-Skeletal Conventional										
Muscular-Skeletal Superficial										
Others (Specify)										

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Additional Comments: _____

Concurrence of CDRI, Office of Device Evaluation (ODE)

David A. Seyman

 (Division Sign-Off)

Division of Reproductive, Abdominal, ENT,
 and Radiological Devices

510(k) Number K994813

Prescription Use _____
 (Per 21 CFR 801.109)

Combison 530D with Probe: S-ACM3-5

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

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P	P		P	N			
Abdominal		P	P	P		P	N			
Intraoperative (Specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (Specify)*										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Muscular-Skeletal Conventional										
Muscular-Skeletal Superficial										
Others (Specify)										

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Additional Comments: _____

Concurrence of CDRE, Office of Device Evaluation (ODE)

David A. Begum
 (Division Sign-Off)
 Division of Reproductive, Abdominal, ENT,
 and Radiological Devices
 510(k) Number 15974813

Prescription Use _____ ✓
 (Per 21 CFR 801.109)

Combison 530D with Probe: S-NLM5-10

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

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intra-Operative (Specify)										
Intraoperative Neurological										
Pediatric		P	P	P		P	N			
Small Organ (Specify)*		P	P	P		P	N			
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		P	P	P		P	N			
Laparoscopic										
Muscular-Skeletal Conventional		P	P	P		P	N			
Muscular-Skeletal Superficial										
Others (Specify)										

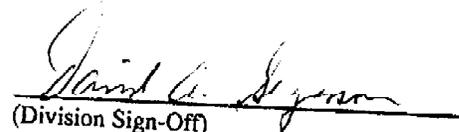
N = new indication; P = previously cleared by FDA; E = added under Appendix E

Additional Comments:

*Specification: thyroid gland, testicles, breast, lymph nodes, salivary gland

(Small Organs with a Region of Interest up to 40mm depth)

Concurrence of CDRE, Office of Device Evaluation (ODE)


 (Division Sign-Off)

Division of Reproductive, Abdominal, ENT,
 and Radiological Devices

510(k) Number K974813

Prescription Use
 (Per 21 CFR 801.109)

Combison 530D with Probe: S-PLM5-10

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

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intra-Operative (Specify)										
Intraoperative Neurological										
Pediatric		P	P	P		P	N			
Small Organ (Specify)*		P	P	P		P	N			
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		P	P	P		P	N			
Laparoscopic										
Muscular-Skeletal Conventional		P	P	P		P	N			
Muscular-Skeletal Superficial										
Others (Specify)										

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Additional Comments:

*Specification: thyroid gland, testicles, breast, lymph nodes, salivary gland
 _____ (Small Organs with a Region of Interest up to 40mm depth)

Concurrence of CDRI, Office of Device Evaluation (ODE)

David A. Segerson

 (Division Sign-Off)
 Division of Reproductive, Abdominal, ENT,
 and Radiological Devices
 510(k) Number K974813

Prescription Use
 (Per 21 CFR 801.109)

Combison 530D with Probe: S-VDW5-8

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

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (specify)
Ophthalmic										
Fetal		P	P	P		P	N			P
Abdominal										
Intraoperative (Specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (Specify)*										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal		P	P	P		P	N			P
Transvaginal		P	P	P		P	N			P
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Muscular-Skeletal Conventional										
Muscular-Skeletal Superficial										
Others (Specify)										

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Additional Comments: Other mode: Volume mode cleared by K940942

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Seymour
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 Division of Reproductive, Abdominal, ENT,
 and Radiological Devices
 510(k) Number K974813

Prescription Use
 (Per 21 CFR 801.109)

Ultrasound Device Indications Statement

510(k) Number: K974813
 Device Name: Combison 530D Probe S-ACP 3-5
 Transducer: 3.5MHz/60D Curved Linear Array Probe

Indications for 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	Amplitude Doppler	Color Velocity Imaging	Combined (B - M)	Other (Specify)
Ophthalmic										
Fetal		E	E	E		E	N		E	
Abdominal		E	E	E		E	N		E	
Intra-Operative (Specify)									E	Note 3
Intra-Operative Neurological										
Pediatric										
Small Organ										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Trans-Rectal										
Trans-Vaginal										
Trans-Urethral										
Intra-Vascular										
Peripheral -Vascular										
Laparoscopic										
Muscular-Skeletal Conventional										
Muscular-Skeletal Superficial										
Others(Specify)										

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Note 3: Includes imaging for guidance of biopsy

Concurrence of CDRH, Office of Device Evaluation(ODE)

Edward A. Seymour
 (Division Sign-Off)
 Division of Reproductive, Abdominal, ENT,
 and Radiological Devices
 510(k) Number K974813

**Indications for Use -
Ultrasound Device Indications Statement**

510(k) Number: **K974813**
 Device Name: **Combison 530D Probe S-ICA 5-8**
 Transducer: **6.5MHz/10R/140D (Endocavity) Curved Linear Array Probe**

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

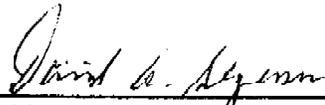
Mode of Operation

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (B - M)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intra-Operative (Specify)										
Intra-Operative Neurological										
Pediatric										
Small Organ										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Trans-Rectal		E	E	E		E	N		E	Note 3
Trans-Vaginal		E	E	E		E	N		E	Note 3
Trans-Urethral										
Intra-Vascular										
Peripheral -Vascular										
Laparoscopic										
Muscular-Skeletal Conventional										
Muscular-Skeletal Superficial										
Others(Specify)										

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Note 3: Includes imaging for guidance of biopsy

Concurrence of CDRH, Office of Device Evaluation(ODE)



 (Division Sign-Off)
 Division of Reproductive, Abdominal, ENT,
 and Radiological Devices
 510(k) Number K974813

✓ Prescription Use (per 21 CFR 801.109)

Ultrasound Device Indications Statement

510(k) Number: K974813
 Device Name: Combison 530D Probe S-NLP 5-10
 Transducer: 7.5 MHz/40mm Linear Array Probe

Indications for 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	Amplitude Doppler	Color Velocity Imaging	Combined (B - M)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intra-Operative (Specify)										
Intra-Operative Neurological										
Pediatric		E	E	E		E	N		E	
Small Organ		E	E	E		E	N		E	Note 2 Note 3
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Trans-Rectal										
Trans-Vaginal										
Trans-Urethral										
Intra-Vascular										
Peripheral -Vascular		E	E	E		E	N		E	
Laparoscopic										
Muscular-Skeletal Conventional										
Muscular-Skeletal Superficial										
Others(Specify)										

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Note 2: Small Organ : breast, thyroid, testes, lymph node, salivary gland.
 Note 3: Includes imaging for guidance of biopsy

Concurrence of CDRH, Office of Device Evaluation(ODE)

David G. [Signature]
 (Division Sign-Off)
 Division of Reproductive, Abdominal, ENT,
 and Radiological Devices
 510(k) Number K974813

✓ Prescription Use (per 21 CFR 801.109)