MAY 3 0 2003

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:**

Bob DePalma (714) 889-3070
Regulatory Affairs
Medison America, Inc.
11075 Knott Ave.
Cypress, CA 90630
Telephone : 714 – 889 - 3000
Facsimile : 714 – 889 – 3079
Email : bdepalma@medison.com

Prepared September 12, 2002

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:

mycolor 202 Diagnostic Ultrasound System and Transducers.

Classification Names:	FR Number	Product Code
Ultrasound Pulsed Echo Imaging System	892.1560	90-IYO
Ultrasonic Pulsed Doppler Imaging System	892.1550	90-IYN
Diagnostic Ultrasound Transducer	892.1570	90-ITX

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

Medison America, Inc. believes that mycolor 202 ultrasound system is substantially equivalent to the currently marketed SA 9900 ultrasound system (K002185) and SA8000 (K013627)

4) **Device Description:**

The mycolor 202 scanner (marketed under the name SonoAce PICO) 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 Doppler, or as a combination of these modes. The mycolor 202 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 mycolor 202 has real time acoustic output display with two basic indices, a mechanical index and a thermal index, which are both automatically displayed.

Seven different models of transducers are available and only one can be connected. 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 Chapter 2 of the Operator manual, and in the software/firmware documentation included in this 510(k) Notification.

The mycolor 202 uses digital beamforming technology, and supports a variety of Linear, Convex, Phased Array and Static probes for a 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 1.0 MHz to 20.0 MHz. These probes can be applied to a variety of clinical applications such as fetal, abdominal, pediatric, small organ, cardiac, trans-rectal, trans-vaginal, peripheral-vascular, and muscular-skeletal. The same clinical uses were cleared for the predicate devices, SA9900 (K002185) and SA8000 (K013627)

The system can be used to measure distances and calculate areas, circumferences and volumes, as well as calculate the expected date of delivery by using BPD

(Biparietal Diameter), HC (Head Circumference), OFD (Occipital Frontal Diameter), FL (Femur Length), AC (Abdominal Circumference), FTA (Fetal Trunk Area), APTD (Anterior Posterior Thoracic Diameter), TTD (Transverse Thoracic Diameter), TAD (Transverse Abdominal Diameter), CRL (Crown Rump Length), GS (Gestational Sac), APD (Anterior-Posterior Abdominal Diameter), AFI (Amniotic Fluid Index), APD (Anterior-Posterior Abdominal Diameter), Cerebellum, CLAV(Clavicle), CM (Cisterna Magna), Ear, FIB (Fibular), Foot, HUM (Humerus), IOD (Inner Ocular Distance), LV (Lateral Ventricle), Mid Cerebral Artery, MP (Middle Phalanx), NF (Nuchal Fold), OOD (Outer Ocular Distance), RAD (Radius Length), TIB (Tibia), ULNA (Ulna Length), Umbilical Artery, YS- Yolk Sac, Cardiac Analysis (volume by area/length, Simpson biplane and single plane, M-mode analysis, Doppler: peak and mean gradients, pressure half time, E/A ratio and continuity equation) and Vascular Analysis (resistive index, pulsatility index, % stenosis, ICA/CCA ratio, Volume flow).

Biopsy guidelines are provided on screen to assist in the collection of tissue samples, using biopsy guide adapters offered as an optional accessory. M-mode uses the scroll display method, which has its images flow from the right to the left on the monitor. The mycolor 202 supports the Cine function (capable of storing up to 256 sequential images) and real-time zoom function to the region-of-interest. The system provides the ability to perform remote viewing of images, without compression, via a DICOM 3.0 compatible output. 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 mycolor 202 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**:

mycolor 202 intended uses as defined FDA guidance documents are:

- Fetal (includes infertility monitoring of follicle development)
- Abdominal
- Pediatric
- Small Organ
- Cardiac (Adult)
- 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 retroperitoneal 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.
- Trans-cranial studies of middle cerebral arteries, internal carotid artery, and vertebral arteries.
- Cardiac studies in adults.
- 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 3 devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 3 0 2003

Medison America, Inc.
% Ms. Laura Danielson
Responsible Third Party Official
TÜV Product Service
1775 Old Highway 8 NW
NEW BRIGHTON MN 55112-1891

Re: K031552
Trade Name: mycolor 202 Diagnostic Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: II
Product Code: 90 IYN, IYO, and ITX
Dated: May 16, 2003
Received: May 19, 2003

Dear Ms. Danielson:

We have reviewed your Section 510(k) premarket 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 mycolor 202 Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

C2-4ES
C3-7ED

HC2-5ED
HL5-9ED
EC4-9ES
EC4-9/10ED

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 Part 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,

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

Enclosure(s)

Section 4.3
INDICATIONS FOR USE

DIAGNOSTIC ULTRASOUND INDICATIONS STATEMENT

510(k) No.:

System: **mycolor 202 Ultrasound System**

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal *(See Note 3)*	P1	P1	P1		P1	Note 1	Note 2, 7, 8
	Abdominal	P1	P1	P1		P1	Note 1	Note 2, 7, 8
	Intra-operative *(See Note 6)*							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P1	P1	P1		P1	Note 1	Note 2, 5, 7, 8
	Small Organ *(See Note 5)*	P1	P1	P1		P1	Note 1	Note 2, 5, 8
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	P	P	P		P	Note 1	Note 2, 8
	Trans-vaginal	P	P	P		P	Note 1	Note 2, 3, 8
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)	P1	P1	P1		P1	Note1	Note 2, 5, 8
	Musculo-skel. (Superfic.)	P1	P1	P1		P1	Note1	Note 2, 5, 8
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult	N	N	N		N	Note1	Note 4
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P1	P1	P1		P1	Note1	Note 2, 5, 8
	Other (spec.)							

N= new indication; P= previously cleared by FDA in K013627 and K002185; P1= previously cleared by FDA in K013627; P2= previously cleared by FDA in K002185; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler (P1, P2)

Note 1: PWD/Color Doppler, PWD/Power Doppler, CWD/Color Doppler, CWD/Power Doppler (P1, P2)

Note 2: Includes imaging for guidance of biopsy (P1, P2)

Note 3: Includes infertility monitoring of follicle development (P1, P2)

Note 4: Color M-mode (P1)

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients (P1, P2)

Note 6: Abdominal organs and peripheral vessel (P1, P2)

Note 7: Tissue Harmonic Imaging (THI) (P1, P2)

Note 8: 3D Imaging (P1, P2)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A. Clymer

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K031552

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:
System: mycolor 202 Ultrasound System
Transducer: C2-4ES / 2-4MHz / 3.0 MHz / 20R Curved Linear Array
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal *(See Note 3)*							
	Abdominal							
	Intra-operative (Abdominal, vascular)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ *(See Note 5)*							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult	N	N	N		N	Note1	Note 4
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA in K013627 and K002185; P1= previously cleared by FDA in K013627; P2= previously cleared by FDA in K002185; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler (P1, P2)

Note 1: PWD/Color Doppler, PWD/Power Doppler, CWD/Color Doppler, CWD/Power Doppler (P1, P2)
Note 2: Includes imaging for guidance of biopsy (P1, P2)
Note 3: Includes infertility monitoring of follicle development (P1, P2)
Note 4: Color M-mode (P1)
Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients (P1, P2)
Note 6: Abdominal organs and peripheral vessel (P1, P2)
Note 7: Tissue Harmonic Imaging (THI) (P1, P2)
Note 8: 3D Imaging (P1, P2)

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

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:
System: mycolor 202 Ultrasound System
Transducer: **C3-7ED** / 3-7MHz / 5.0 MHz / 50R Curved Linear Array
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal *(See Note 3)*	P1	P1	P1		P1	Note 1	Note 2, 7, 8
	Abdominal	P1	P1	P1		P1	Note 1	Note 2, 7, 8
	Intra-operative (Abdominal, vascular)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P1	P1	P1		P1	Note 1	Note 2, 7, 8
	Small Organ *(See Note 5)*							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA in K013627 and K002185; P1= previously cleared by FDA in K013627; P2= previously cleared by FDA in K002185; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler (P1, P2)

Note 1: PWD/Color Doppler, PWD/Power Doppler, CWD/Color Doppler, CWD/Power Doppler (P1, P2)
Note 2: Includes imaging for guidance of biopsy (P1, P2)
Note 3: Includes infertility monitoring of follicle development (P1, P2)
Note 4: Color M-mode (P1)
Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients (P1, P2)
Note 6: Abdominal organs and peripheral vessel (P1, P2)
Note 7: Tissue Harmonic Imaging (THI) (P1, P2)
Note 8: 3D Imaging (P1, P2)

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

K031552

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:
System: mycolor 202 Ultrasound System
Transducer: **HC2-5ED** / 2-5MHz / 3.5 MHz / 40R Curved Linear Array
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal *(See Note 3)*	N	N	N		N	Note1	Note 2, 8
	Abdominal	N	N	N		N	Note1	Note 2, 8
	Intra-operative (Abdominal, vascular)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	N	N	N		N	Note1	Note 2, 8
	Small Organ *(See Note 5)*							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA in K013627 and K002185; P1= previously cleared by FDA in K013627; P2= previously cleared by FDA in K002185; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler (P1, P2)

Note 1: PWD/Color Doppler, PWD/Power Doppler, CWD/Color Doppler, CWD/Power Doppler (P1, P2)
Note 2: Includes imaging for guidance of biopsy (P1, P2)
Note 3: Includes infertility monitoring of follicle development (P1, P2)
Note 4: Color M-mode (P1)
Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients (P1, P2)
Note 6: Abdominal organs and peripheral vessel (P1, P2)
Note 7: Tissue Harmonic Imaging (THI) (P1, P2)
Note 8: 3D Imaging (P1, P2)

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

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:
System: mycolor 202 Ultrasound System
Transducer: **HL5-9ED** / 5-9MHz / 7.5 MHz / 40mm Linear Array
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal *(See Note 3)*							
	Abdominal							
	Intra-operative (Abdominal, vascular)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P1	P1	P1		P1	Note 1	Note 2, 5, 8
	Small Organ *(See Note 5)*	P1	P1	P1		P1	Note 1	Note 2, 5, 8
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)	P1	P1	P1		P1	Note1	Note 2, 5, 8
	Musculo-skel. (Superfic.)	P1	P1	P1		P1	Note1	Note 2, 5, 8
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P1	P1	P1		P1	Note1	Note 2, 5, 8
	Other (spec.)							

N= new indication; P= previously cleared by FDA in K013627 and K002185; P1= previously cleared by FDA in K013627; P2= previously cleared by FDA in K002185; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler (P1, P2)

Note 1: PWD/Color Doppler, PWD/Power Doppler, CWD/Color Doppler, CWD/Power Doppler (P1, P2)
Note 2: Includes imaging for guidance of biopsy (P1, P2)
Note 3: Includes infertility monitoring of follicle development (P1, P2)
Note 4: Color M-mode (P1)
Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients (P1, P2)
Note 6: Abdominal organs and peripheral vessel (P1, P2)
Note 7: Tissue Harmonic Imaging (THI) (P1, P2)
Note 8: 3D Imaging (P1, P2)

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

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:
System: mycolor 202 Ultrasound System
Transducer: **EC4-9ES** / 4-9MHz / 6.5 MHz / 10R Endocavity Curved Linear Array
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal *(See Note 3)*							
	Abdominal							
	Intra-operative (Abdominal, vascular)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ *(See Note 5)*							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	P	P	P		P	Note 1	Note 2, 8
	Trans-vaginal	P	P	P		P	Note 1	Note 2, 3, 8
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA in K013627 and K002185; P1= previously cleared by FDA in K013627; P2= previously cleared by FDA in K002185; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler (P1, P2)

Note 1: PWD/Color Doppler, PWD/Power Doppler, CWD/Color Doppler, CWD/Power Doppler (P1, P2)
Note 2: Includes imaging for guidance of biopsy (P1, P2)
Note 3: Includes infertility monitoring of follicle development (P1, P2)
Note 4: Color M-mode (P1)
Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients (P1, P2)
Note 6: Abdominal organs and peripheral vessel (P1, P2)
Note 7: Tissue Harmonic Imaging (THI) (P1, P2)
Note 8: 3D Imaging (P1, P2)

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

David A. Lyman

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K031352

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:
System: mycolor 202 Ultrasound System
Transducer: **EC4-9/10ED** / 4-9MHz / 6.5 MHz / 10R Endocavity Curved Linear Array
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal *(See Note 3)*							
	Abdominal							
	Intra-operative (Abdominal, vascular)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ *(See Note 5)*							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	N	N	N		N	Note 1	Note 2, 8
	Trans-vaginal	N	N	N		N	Note 1	Note 2, 3, 8
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA in K013627 and K002185; P1= previously cleared by FDA in K013627; P2= previously cleared by FDA in K002185; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler (P1, P2)

Note 1: PWD/Color Doppler, PWD/Power Doppler, CWD/Color Doppler, CWD/Power Doppler (P1, P2)
Note 2: Includes imaging for guidance of biopsy (P1, P2)
Note 3: Includes infertility monitoring of follicle development (P1, P2)
Note 4: Color M-mode (P1)
Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients (P1, P2)
Note 6: Abdominal organs and peripheral vessel (P1, P2)
Note 7: Tissue Harmonic Imaging (THI) (P1, P2)
Note 8: 3D Imaging (P1, P2)

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 K031552