K061637

JUL 25 2006

510(k) Summary

1.0 SUBMITTER INFORMATION

1.1 Submitter: SHIMADZU MEDICAL SYSTEMS
20101 South Vermont Ave.
Torrance, CA 90502-1328
PH: 310-217-8855
FX: 310-217-8869

1.2 Contact: Randal Walker

1.3 Date: MAR. 17.2006

2.0 DEVICE NAME

2.1 Proprietary Name:	SDU-2200Pro
2.2 Common Name:	Ultrasound Imaging System
2.3 Classification:	Ultrasonic Pulsed Doppler Imaging System FR # 892.1550, Product Code 90-IYN Ultrasonic Pulsed Echo Imaging System FR # 892.1560, Product Code 90-IYO Diagnostic Ultrasound Transducer FR # 892.1570, Product Code 90-ITX
2.4 Predicate Device:	Shimadzu SDU-2200 (K003514, Feb./12/01)

3.0 DEVICE DESCRIPTION

The SDU-2200Pro is a mobile diagnostic ultrasound system. This system has flat linear array, convex linear and sector probe with a frequency range of approximately 2 to 15 MHz. It has B mode, M mode, Pulsed Doppler mode, Continuous Doppler mode, Color mode, or in a combination of modes.

4.0 INTENDED USE

The SDU-2200Pro is intended for the following applications:

Fetal, Abdominal, Pediatric, Small Organs (Specify), Neonatal Cephalic, Adult Cephalic, Cardiac, Transrectal, Transvaginal, Peripheral Vascular, Musculo-skeletal Superficial and Musculo-skeletal Conventional.

5.0 SAFETY CONSIDERATIONS

SDU-2200Pro has been designed to meet the following voluntary and measurement standards:

- IEC 60601-1 Safety of Medical Electric Equipment
- UL60601-1:2003 Medical Electrical Equipment Part I : General Requirements for Safety
- AIUM NEMA UD2 Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment
- Acoustic Output Measurement and Labeling Standard for Diagnostic Ultrasound Equipment Revision 1 (AIUM 1998)
- AIUM NEMA UD3 Standard for Real-time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 25 2006

Mr. Randal Walker
National Service Manager
Shimadzu Medical Systems
20101 South Vermont Ave.
TORRANCE CA 90502-1328

Re: K061637
Trade Name: Diagnostic Ultrasound System SDU-2200Pro, 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: IYN, IYO, and ITX
Dated: March 17, 2006
Received: June 13, 2006

Dear Mr. Walker:

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 Diagnostic Ultrasound System SDU-2200Pro, System, as described in your premarket notification:

Transducer Model Number

L040-075U	VA13R-050U	UB10R-065U
L040-120U	VA20R-035U	EC11R-055U
L040-120HU	VA40R-035U	S011-050U
L070-075U	VA40R-035HU	S017-035U
L072-050U	VA57R-0375WU	S020-025U
VA11R-055U	VA57R-0375HU	
VA13R-035U	TV11R-055U	

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 (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

If you have any questions regarding the content of this letter, please contact Andrew Kang, M.D. at (301) 594-1212.

Sincerely yours,

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

Enclosure(s)

Prescription Use (Per 21 CFR 801.109)

Ultrasound Device Indications Statement Page 1 of 20 .

510(k) Number (if known) : K061637

Device Name : Diagnostic Ultrasound System SDU-2200Pro, system

Fill out one form for each ultrasound system or transducer.

Indications for use: Diagnostic ultrasound imaging or Doppler analysis of the human body as follows:

Mode of Operation

Clinical Application	*A*	*B*	*M*	*PWD*	*CWD*	*Color Doppler*	*Power (Amplitude) Doppler*	*Color Velocity Imaging*	*Combined (Specify)***	*Tissue Harmonic Imaging*	*Other (Specify)*
Ophthalmic											
Fetal		N	N	N		N	N	N	N	N	
Abdominal		N	N	N		N	N	N	N	N	
Intra-operative (Specify)											
Intra-operative Neurological											
Pediatric											
*Small Organ (Specify) **		N	N	N		N	N	N	N	N	
Neonatal Cephalic											
Adult Cephalic											
Cardiac		N	N	N		N	N	N	N	N	
Transesophageal											
Transrectal		N	N	N		N	N	N	N	N	
Transvaginal		N	N	N		N	N	N	N	N	
Transurethral											
Intravascular											
Peripheral Vascular		N	N	N		N	N	N	N	N	
Laparoscopic											
Musculo-skeletal Conventional		N	N	N		N	N	N	N	N	
Musculo-skeletal Superficial		N	N	N		N	N	N	N	N	
Other (Specify)											

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

Other Indications or Modes:

* Thyroid, Testicles, Breast

** B/M, B/PWD, CFM(B)/PWD, CFM(B)/CFM(M)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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
510(k) Number K061637

Prescription Use (Per 21 CFR 801.109)

Ultrasound Device Indications Statement Page 2 of 20 .

510(k) Number (if known) : K061637 .

Device Name : Diagnostic Ultrasound System SDU-2200Pro, L040-075U

Fill out one form for each ultrasound system or transducer.

Indications for use: Diagnostic ultrasound imaging or Doppler analysis of the human body as follows:

Mode of Operation

Clinical Application	*A*	*B*	*M*	*PWD*	*CWD*	*Color Doppler*	*Power (Amplitude) Doppler*	*Color Velocity Imaging*	*Combined (Specify)***	*Tissue Harmonic Imaging*	*Other (Specify)*
Ophthalmic											
Fetal											
Abdominal											
Intra-operative (Specify)											
Intra-operative Neurological											
Pediatric											
*Small Organ (Specify) **		N	N	N		N	N	N	N	N	
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular		N	N	N		N	N	N	N	N	
Laparoscopic											
Musculo-skeletal Conventional		N	N	N		N	N	N	N	N	
Musculo-skeletal Superficial		N	N	N		N	N	N	N	N	
Other (Specify)											

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

Other Indications or Modes:

* Thyroid, Testicles, Breast

** B/M, B/PWD, CFM(B)/PWD, CFM(B)/CFM(M)

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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

510(k) Number K061637

Prescription Use (Per 21 CFR 801.109)

Ultrasound Device Indications Statement Page 3 of 20 .

510(k) Number (if known) : K061637 .

Device Name : Diagnostic Ultrasound System SDU-2200Pro, L040-120U

Fill out one form for each ultrasound system or transducer.

Indications for use: Diagnostic ultrasound imaging or Doppler analysis of the human body as follows:

Mode of Operation

Clinical Application	*A*	*B*	*M*	*PWD*	*CWD*	*Color Doppler*	*Power (Amplitude) Doppler*	*Color Velocity Imaging*	*Combined (Specify)***	*Tissue Harmonic Imaging*	*Other (Specify)*
Ophthalmic											
Fetal											
Abdominal											
Intra-operative (Specify)											
Intra-operative Neurological											
Pediatric											
*Small Organ (Specify) **		N	N	N		N	N	N	N	N	
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular		N	N	N		N	N	N	N	N	
Laparoscopic											
Musculo-skeletal Conventional		N	N	N		N	N	N	N	N	
Musculo-skeletal Superficial		N	N	N		N	N	N	N	N	
Others (Specify)											

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

Other Indications or Modes:

* Thyroid, Testicles, Breast

** B/M, B/PWD, CFM(B)/PWD, CFM(B)/CFM(M)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of Reproductive, Abdominal, and Radiological Devices

510(k) Number K061637

Prescription Use (Per 21 CFR 801.109)

Ultrasound Device Indications Statement Page 4 of 20 .

510(k) Number (if known) : K061637 .
Device Name : Diagnostic Ultrasound System SDU-2200Pro, L040-120HU

Fill out one form for each ultrasound system or transducer.

Indications for use: Diagnostic ultrasound imaging or Doppler analysis of the human body as follows:

Mode of Operation

Clinical Application	*A*	*B*	*M*	*PWD*	*CWD*	*Color Doppler*	*Power (Amplitude) Doppler*	*Color Velocity Imaging*	*Combined (Specify)***	*Tissue Harmonic Imaging*	*Other (Specify)*
Ophthalmic											
Fetal											
Abdominal											
Intra-operative (Specify)											
Intra-operative Neurological											
Pediatric											
*Small Organ (Specify) **		N	N	N		N	N	N	N	N	
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular		N	N	N		N	N	N	N	N	
Laparoscopic											
Musculo-skeletal Conventional		N	N	N		N	N	N	N	N	
Musculo-skeletal Superficial		N	N	N		N	N	N	N	N	
Others (Specify)											

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

Other Indications or Modes:

* Thyroid, Testicles, Breast

** B/M, B/PWD, CFM(B)/PWD, CFM(B)/CFM(M)

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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
510(k) Number K061637

Prescription Use (Per 21 CFR 801.109)

Ultrasound Device Indications Statement .

510(k) Number (if known) : K061637.

Device Name : Diagnostic Ultrasound System SDU-2200Pro, L070-075U

Fill out one form for each ultrasound system or transducer.

Indications for use: Diagnostic ultrasound imaging or Doppler analysis of the human body as follows:

Mode of Operation

Clinical Application	*A*	*B*	*M*	*PWD*	*CWD*	*Color Doppler*	*Power (Amplitude) Doppler*	*Color Velocity Imaging*	*Combined (Specify)***	*Tissue Harmonic Imaging*	*Other (Specify)*
Ophthalmic											
Fetal											
Abdominal											
Intra-operative (Specify)											
Intra-operative Neurological											
Pediatric											
*Small Organ (Specify) **		N	N	N		N	N	N	N	N	
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular		N	N	N		N	N	N	N	N	
Laparoscopic											
Musculo-skeletal Conventional		N	N	N		N	N	N	N	N	
Musculo-skeletal Superficial		N	N	N		N	N	N	N	N	
Others (Specify)											

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

Other Indications or Modes:

* Thyroid, Testicles, Breast

** B/M, B/PWD, CFM(B)/PWD, CFM(B)/CFM(M)

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Division of Reproductive, Abdominal, and Radiological Devices

510(k) Number K061637

Prescription Use ✓
(Per 21 CFR 801.109)

Prescription Use (Per 21 CFR 801.109)

Ultrasound Device Indications Statement .

510(k) Number (if known) : K061637.

Device Name : Diagnostic Ultrasound System SDU-2200Pro, L072-050U

Fill out one form for each ultrasound system or transducer.

Indications for use: Diagnostic ultrasound imaging or Doppler analysis of the human body as follows:

Mode of Operation

Clinical Application	*A*	*B*	*M*	*PWD*	*CWD*	*Color Doppler*	*Power (Amplitude) Doppler*	*Color Velocity Imaging*	*Combined (Specify)***	*Tissue Harmonic Imaging*	*Other (Specify)*
Ophthalmic											
Fetal											
Abdominal											
Intra-operative (Specify)											
Intra-operative Neurological											
Pediatric											
*Small Organ (Specify) **		N	N	N		N	N	N	N	N	
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular		N	N	N		N	N	N	N	N	
Laparoscopic											
Musculo-skeletal Conventional		N	N	N		N	N	N	N	N	
Musculo-skeletal Superficial											
Others (Specify)											

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

Other Indications or Modes:

* Thyroid, Testicles, Breast

** B/M, B/PWD, CFM(B)/PWD, CFM(B)/CFM(M)

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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
510(k) Number K061637

Prescription Use (Per 21 CFR 801.109)

Ultrasound Device Indications Statement .

510(k) Number (if known) : K061637

Device Name : Diagnostic Ultrasound System SDU-2200Pro, VA11R-055U

Fill out one form for each ultrasound system or transducer.

Indications for use: Diagnostic ultrasound imaging or Doppler analysis of the human body as follows:

Mode of Operation

Clinical Application	*A*	*B*	*M*	*PWD*	*CWD*	*Color Doppler*	*Power (Amplitude) Doppler*	*Color Velocity Imaging*	*Combined (Specify)***	*Tissue Harmonic Imaging*	*Other (Specify)*
Ophthalmic											
Fetal		N	N	N		N	N	N	N	N	
Abdominal		N	N	N		N	N	N	N	N	
Intra-operative (Specify)											
Intra-operative Neurological											
Pediatric		N	N	N		N	N	N	N	N	
*Small Organ (Specify) * *											
Neonatal Cephalic		N	N	N		N	N	N	N	N	
Adult Cephalic		N	N	N		N	N	N	N	N	
Cardiac		N	N	N		N	N	N	N	N	
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular											
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Others (Specify)											

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

Other Indications or Modes:

** B/M, B/PWD, CFM(B)/PWD,CFM(B)/CFM(M)

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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
510(k) Number K061637

Prescription Use (Per 21 CFR 801.109)

Ultrasound Device Indications Statement Page 8 of 20 .

510(k) Number (if known) : K061637

Device Name : Diagnostic Ultrasound System SDU-2200Pro, VA13R-035U

Fill out one form for each ultrasound system or transducer.

Indications for use: Diagnostic ultrasound imaging or Doppler analysis of the human body as follows:

Mode of Operation

Clinical Application	*A*	*B*	*M*	*PWD*	*CWD*	*Color Doppler*	*Power (Amplitude) Doppler*	*Color Velocity Imaging*	*Combined (Specify)***	*Tissue Harmonic Imaging*	*Other (Specify)*
Ophthalmic											
Fetal		N	N	N		N	N	N	N	N	
Abdominal		N	N	N		N	N	N	N	N	
Intra-operative (Specify)											
Intra-operative Neurological											
Pediatric											
*Small Organ (Specify) **											
Neonatal Cephalic											
Adult Cephalic											
Cardiac		N	N	N		N	N	N	N	N	
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular											
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Others (Specify)											

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Other Indications or Modes:

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510(k) Number K061637

Prescription Use ✓
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Prescription Use (Per 21 CFR 801.109)

Ultrasound Device Indications Statement Page 9 of 20 .

510(k) Number (if known) : K061637

Device Name : Diagnostic Ultrasound System SDU-2200Pro, VA13R-050U

Fill out one form for each ultrasound system or transducer.

Indications for use: Diagnostic ultrasound imaging or Doppler analysis of the human body as follows:

Mode of Operation

Clinical Application	*A*	*B*	*M*	*PWD*	*CWD*	*Color Doppler*	*Power (Amplitude) Doppler*	*Color Velocity Imaging*	*Combined (Specify)***	*Tissue Harmonic Imaging*	*Other (Specify)*
Ophthalmic											
Fetal		N	N	N		N	N	N	N	N	
Abdominal		N	N	N		N	N	N	N	N	
Intra-operative (Specify)											
Intra-operative Neurological											
Pediatric											
*Small Organ (Specify) **											
Neonatal Cephalic											
Adult Cephalic											
Cardiac		N	N	N		N	N	N	N	N	
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular											
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Others (Specify)											

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

Other Indications or Modes:

** B/M, B/PWD, CFM(B)/PWD,CFM(B)/CFM(M)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices

510(k) Number K061637

Prescription Use ✓
(Per 21 CFR 801.109)

Prescription Use (Per 21 CFR 801.109)

Ultrasound Device Indications Statement Page 10 of 20 .

510(k) Number (if known) : K061637 .

Device Name : Diagnostic Ultrasound System SDU-2200Pro, VA20R-035U

Fill out one form for each ultrasound system or transducer.

Indications for use: Diagnostic ultrasound imaging or Doppler analysis of the human body as follows:

Mode of Operation

Clinical Application	*A*	*B*	*M*	*PWD*	*CWD*	*Color Doppler*	*Power (Amplitude) Doppler*	*Color Velocity Imaging*	*Combined (Specify)***	*Tissue Harmonic Imaging*	*Other (Specify)*
Ophthalmic											
Fetal		N	N	N		N	N	N	N	N	
Abdominal		N	N	N		N	N	N	N	N	
Intra-operative (Specify)											
Intra-operative Neurological											
Pediatric											
*Small Organ (Specify) **											
Neonatal Cephalic											
Adult Cephalic											
Cardiac		N	N	N		N	N	N	N	N	
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular											
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Others (Specify)											

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

Other Indications or Modes:

** B/M, B/PWD, CFM(B)/PWD,CFM(B)/CFM(M)

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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
510(k) Number K061637

Prescription Use (Per 21 CFR 801.109)

Ultrasound Device Indications Statement Page 11 of 20 .

510(k) Number (if known) : K061637 .

Device Name : Diagnostic Ultrasound System SDU-2200Pro, VA40R-035U

Fill out one form for each ultrasound system or transducer.

Indications for use: Diagnostic ultrasound imaging or Doppler analysis of the human body as follows:

Mode of Operation

Clinical Application	*A*	*B*	*M*	*PWD*	*CWD*	*Color Doppler*	*Power (Amplitude) Doppler*	*Color Velocity Imaging*	*Combined (Specify)***	*Tissue Harmonic Imaging*	*Other (Specify)*
Ophthalmic											
Fetal		N	N	N		N	N	N	N	N	
Abdominal		N	N	N		N	N	N	N	N	
Intra-operative (Specify)											
Intra-operative Neurological											
Pediatric											
*Small Organ (Specify) **											
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular											
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Others (Specify)											

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

Other Indications or Modes:

** B/M, B/PWD, CFM(B)/PWD,CFM(B)/CFM(M)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

Marilyn Hanyok
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K061637

Prescription Use (Per 21 CFR 801.109)

Ultrasound Device Indications Statement Page 12 of 20 .

510(k) Number (if known) : K061637

Device Name : Diagnostic Ultrasound System SDU-2200Pro, VA40R-035HU

Fill out one form for each ultrasound system or transducer.

Indications for use: Diagnostic ultrasound imaging or Doppler analysis of the human body as follows:

Mode of Operation

Clinical Application	*A*	*B*	*M*	*PWD*	*CWD*	*Color Doppler*	*Power (Amplitude) Doppler*	*Color Velocity Imaging*	*Combined (Specify)***	*Tissue Harmonic Imaging*	*Other (Specify)*
Ophthalmic											
Fetal		N	N	N		N	N	N	N	N	
Abdominal		N	N	N		N	N	N	N	N	
Intra-operative (Specify)											
Intra-operative Neurological											
Pediatric											
*Small Organ (Specify) **											
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular											
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Others (Specify)											

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

Other Indications or Modes:

** B/M, B/PWD, CFM(B)/PWD,CFM(B)/CFM(M)

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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

510(k) Number K061637

Prescription Use (Per 21 CFR 801.109)

Ultrasound Device Indications Statement Page 13 of 20 .

510(k) Number (if known) : K061637

Device Name : Diagnostic Ultrasound System SDU-2200Pro, VA57R-0375WU

Fill out one form for each ultrasound system or transducer.

Indications for use: Diagnostic ultrasound imaging or Doppler analysis of the human body as follows:

Mode of Operation

Clinical Application	*A*	*B*	*M*	*PWD*	*CWD*	*Color Doppler*	*Power (Amplitude) Doppler*	*Color Velocity Imaging*	*Combined (Specify)***	*Tissue Harmonic Imaging*	*Other (Specify)*
Ophthalmic											
Fetal		N	N	N		N	N	N	N	N	
Abdominal		N	N	N		N	N	N	N	N	
Intra-operative (Specify)											
Intra-operative Neurological											
Pediatric											
*Small Organ (Specify) **											
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular											
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Others (Specify)											

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

Other Indications or Modes:

** B/M, B/PWD, CFM(B)/PWD,CFM(B)/CFM(M)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices

510(k) Number K061637

Prescription Use ✓
(Per 21 CFR 801.109)

Prescription Use (Per 21 CFR 801.109)

Ultrasound Device Indications Statement Page 14 of 20 .

510(k) Number (if known) : K061637 .

Device Name : Diagnostic Ultrasound System SDU-2200Pro, VA57R-0375HU

Fill out one form for each ultrasound system or transducer.

Indications for use: Diagnostic ultrasound imaging or Doppler analysis of the human body as follows:

Mode of Operation

Clinical Application	*A*	*B*	*M*	*PWD*	*CWD*	*Color Doppler*	*Power (Amplitude) Doppler*	*Color Velocity Imaging*	*Combined (Specify)***	*Tissue Harmonic Imaging*	*Other (Specify)*
Ophthalmic											
Fetal		N	N	N		N	N	N	N	N	
Abdominal		N	N	N		N	N	N	N	N	
Intra-operative (Specify)											
Intra-operative Neurological											
Pediatric											
*Small Organ (Specify) **											
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular											
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Others (Specify)											

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

Other Indications or Modes:

** B/M, B/PWD, CFM(B)/PWD,CFM(B)/CFM(M)

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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
510(k) Number K061637

Prescription Use (Per 21 CFR 801.109)

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510(k) Number (if known) : K061637 .

Device Name : Diagnostic Ultrasound System SDU-2200Pro, TV11R-055U

Fill out one form for each ultrasound system or transducer.

Indications for use: Diagnostic ultrasound imaging or Doppler analysis of the human body as follows:

Mode of Operation

Clinical Application	*A*	*B*	*M*	*PWD*	*CWD*	*Color Doppler*	*Power (Amplitude) Doppler*	*Color Velocity Imaging*	*Combined (Specify)***	*Tissue Harmonic Imaging*	*Other (Specify)*
Ophthalmic											
Fetal		N	N	N		N	N	N	N	N	
Abdominal											
Intra-operative (Specify)											
Intra-operative Neurological											
Pediatric											
*Small Organ (Specify) **											
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Transesophageal											
Transrectal		N	N	N		N	N	N	N	N	
Transvaginal		N	N	N		N	N	N	N	N	
Transurethral											
Intravascular											
Peripheral Vascular											
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Others (Specify)											

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

Other Indications or Modes:

** B/M, B/PWD, CFM(B)/PWD,CFM(B)/CFM(M)

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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
510(k) Number K061637

Prescription Use (Per 21 CFR 801.109)

Ultrasound Device Indications Statement Page 16 of 20 .

510(k) Number (if known) : K061637 .

Device Name : Diagnostic Ultrasound System SDU-2200Pro, UB10R-065U

Fill out one form for each ultrasound system or transducer.

Indications for use: Diagnostic ultrasound imaging or Doppler analysis of the human body as follows:

Mode of Operation

Clinical Application	*A*	*B*	*M*	*PWD*	*CWD*	*Color Doppler*	*Power (Amplitude) Doppler*	*Color Velocity Imaging*	*Combined (Specify)***	*Tissue Harmonic Imaging*	*Other (Specify)*
Ophthalmic											
Fetal											
Abdominal											
Intra-operative (Specify)											
Intra-operative Neurological											
Pediatric											
*Small Organ (Specify) **											
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Transesophageal											
Transrectal		N	N	N		N	N	N	N	N	
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular											
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Others (Specify)											

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

Other Indications or Modes:

** B/M, B/PWD, CFM(B)/PWD,CFM(B)/CFM(M)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K061637

Prescription Use (Per 21 CFR 801.109)

Ultrasound Device Indications Statement Page 17 of 20 .

510(k) Number (if known) : K061637 .
Device Name : Diagnostic Ultrasound System SDU-2200Pro, EC11R-055U

Fill out one form for each ultrasound system or transducer.

Indications for use: Diagnostic ultrasound imaging or Doppler analysis of the human body as follows:

Mode of Operation

Clinical Application	*A*	*B*	*M*	*PWD*	*CWD*	*Color Doppler*	*Power (Amplitude) Doppler*	*Color Velocity Imaging*	*Combined (Specify)***	*Tissue Harmonic Imaging*	*Other (Specify)*
Ophthalmic											
Fetal		N	N	N		N	N	N	N	N	
Abdominal											
Intra-operative (Specify)											
Intra-operative Neurological											
Pediatric											
*Small Organ (Specify) * *											
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Transesophageal											
Transrectal		N	N	N		N	N	N	N	N	
Transvaginal		N	N	N		N	N	N	N	N	
Transurethral											
Intravascular											
Peripheral Vascular											
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Others (Specify)											

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

Other Indications or Modes:

** B/M, B/PWD, CFM(B)/PWD,CFM(B)/CFM(M)

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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
510(k) Number K061637

510(k) Number (if known) : K061637 .
Device Name : Diagnostic Ultrasound System SDU-2200Pro, S011-050U

Fill out one form for each ultrasound system or transducer.

Indications for use: Diagnostic ultrasound imaging or Doppler analysis of the human body as follows:

Mode of Operation

Clinical Application	*A*	*B*	*M*	*PWD*	*CWD*	*Color Doppler*	*Power (Amplitude) Doppler*	*Color Velocity Imaging*	*Combined (Specify)***	*Tissue Harmonic Imaging*	*Other (Specify)*
Ophthalmic											
Fetal											
Abdominal				N		N	N			N	
Intra-operative (Specify)											
Intra-operative Neurological											
Pediatric		N	N	N	N	N	N	N	N	N	
*Small Organ (Specify) **											
Neonatal Cephalic											
Adult Cephalic											
Cardiac		N	N	N	N	N	N	N	N	N	
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular											
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Others (Specify)											

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

Other Indications or Modes:

** B/M, B/PWD, CFM(B)/PWD,CFM(B)/PWD,CFM(B)/CFM(M),B/CWD,CFM(B)/CWD

Harmonic Imaging

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K061637

Prescription Use (Per 21 CFR 801.109)

Ultrasound Device Indications Statement Page 19 of 20 .

510(k) Number (if known) : K061637 .

Device Name : Diagnostic Ultrasound System SDU-2200Pro, S017-035U

Fill out one form for each ultrasound system or transducer.

Indications for use: Diagnostic ultrasound imaging or Doppler analysis of the human body as follows:

Mode of Operation

Clinical Application	*A*	*B*	*M*	*PWD*	*CWD*	*Color Doppler*	*Power (Amplitude) Doppler*	*Color Velocity Imaging*	*Combined (Specify)***	*Tissue Harmonic Imaging*	*Other (Specify)*
Ophthalmic											
Fetal											
Abdominal				N		N	N			N	
Intra-operative (Specify)											
Intra-operative Neurological											
Pediatric											
*Small Organ (Specify) **											
Neonatal Cephalic											
Adult Cephalic											
Cardiac		N	N	N	N	N	N	N	N	N	
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular											
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Others (Specify)											

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

Other Indications or Modes:

** B/M, B/PWD, CFM(B)/PWD,CFM(B)/PWD,CFM(B)/CFM(M),B/CWD,CFM(B)/CWD

Harmonic Imaging

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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Division of Reproductive, Abdominal, and Radiological Devices

510(k) Number K061637

Prescription Use (Per 21 CFR 801.109)

Ultrasound Device Indications Statement Page 20 of 20 .

510(k) Number (if known) : K061637 .
Device Name : Diagnostic Ultrasound System SDU-2200Pro, S020-025U

Fill out one form for each ultrasound system or transducer.

Indications for use: Diagnostic ultrasound imaging or Doppler analysis of the human body as follows:

Mode of Operation

Clinical Application	*A*	*B*	*M*	*PWD*	*CWD*	*Color Doppler*	*Power (Amplitude) Doppler*	*Color Velocity Imaging*	*Combined (Specify)***	*Tissue Harmonic Imaging*	*Other (Specify)*
Ophthalmic											
Fetal											
Abdominal				N		N	N			N	
Intra-operative (Specify)											
Intra-operative Neurological											
Pediatric											
*Small Organ (Specify) **											
Neonatal Cephalic											
Adult Cephalic											
Cardiac		N	N	N	N	N	N	N	N	N	
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular											
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Others (Specify)											

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

Other Indications or Modes:

** B/M, B/PWD, CFM(B)/PWD,CFM(B)/PWD,CFM(B)/CFM(M),B/CWD,CFM(B)/CWD

Harmonic Imaging

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K061637

Prescription Use ✓
(Per 21 CFR 801.109)