LO61637

JUL 2 5 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. 1 7. 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



Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

JUL 2 5 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:



Protecting and Promoting Public Health

Transducer Model Number

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

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 <u>Federal Register</u>.

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

Page 3 - Mr. Walker

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 <u>http://www.fda.gov/cdrh/industry/support/index.html</u>

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

Sincerely yours,

Vancy C migden

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

Enclosure(s)

Ultrasound Device Indications Statement Page <u>1</u> of <u>20</u>.

510(k) Number (if known) : <u>K061637</u> Device Name : <u>Diagnostic Ultrasound System SDU-2200Pro, system</u>

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:

Clinical Application	A	B	М	₽₩D	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)**	Tissue Harmonic Imaging	Other (Specify)
Ophthalmic										1	
Fetal		N	N	N		N	N	N	N	<u>N</u>	
Abdominal		N	N	N		N	N	N	N	N	
Intra-operative (Specify)											
Intra-operative Neurological											
Pediatric		T									<u> </u>
Small Organ (Specify) *		N	N	N		N	N	N	N	N	
Neonatal Cephalic											
Adult Cephalic	1	1	1								
Cardiac		Ν	N	N		N	N	N	N	<u>N</u>	1
Transesophageal											ļ
Transrectal	1	N	N	N		N	<u>N</u>	N	N	<u>N</u>	
Transvaginal		N	N	N		N	N	N	N	N	<u> </u>
Transurethral		1	Í								
Intravascular										1	
Peripheral Vascular		N	N	N		N	N	N	N	N	1
Laparoscopic		1.							_	· · ·	
Musculo-skeletal Conventional		N	И	N		N	N	N	N	N	
Musculo-skeletal Superficial		N	N	N		N	N	N	N	N	
Other (Specify)	1	T	1					1			<u> </u>

Mode of Operation

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)

Olapton.

(Division Sign-Off) Division of Reproductive, Abdominal, and Radiological Devices 510(k) Number <u>KO6/637</u>

Ultrasound Device Indications Statement Page 2 of 20.

K061637 510(k) Number (if known) :

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:

Clinical Application	A	B	м	PWD	CWD	Color Doppl e r	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)**	Tissue Harmoni c Imaging	Other (Specify)
Ophthalmic							·	 		 	
Fetal	L	I			1		<u> </u>	 		<u> </u>	<u> </u>
Abdominal					ļ			<u> </u>			
Intra-operative (Specify)											ļ
Intra-operative Neurological								 			
Pediatric		1					<u> </u>				
Small Organ (Specify) *		N	N	N		N	N	N	N	N	<u> </u>
Neonatal		1						1			
Cephalic	1										
Adult Cephalic	- ·		1	L						_ <u>_</u>	
Cardiac						<u> </u>					
Transesophageal								<u> </u>			_ <u>_</u>
Transrectal				<u> </u>						_ <u></u>	
Transvaginal		<u> </u>	1								
Transurethral		_		1		<u> </u>	_ 	<u> </u>			
Intravascular	1			.l			<u> </u>				
Peripheral Vascular		N	N	N		<u>N</u>	<u> </u>	<u>N</u>	N		
Laparoscopic	1			ļ	<u> </u>	_ <u></u>		N	N		
Musculo-skeletal Conventional		N	N	N		N	N				
Musculo-skeletal Superficial		N	N	N		N	N	N	N	N	
Other (Specify)	1-	1	1							<u></u>	

Mode of Operation

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)

(Division Sign-Off) Division of Reproductive, Abdominal, and Radiological Devices 1061637

510(k) Number

Prescription Use _ (Per 21 CFR 801.109)

Ultrasound Device Indications Statement Page <u>3</u> of <u>20</u>.

510(k) Number (if known) : <u>K061637</u> Device Name : <u>Diagnostic Ultrasound System SDU-2200Pro, L040-120U</u>

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:

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)**	Tissue Harmonic Imaging	Other (Specify)
Ophthalmic							1		1	<u></u>	<u> </u>
Fetal										<u> </u>	1
Abdominal		1	<u> </u>								
Intra-operative (Specify)											
Intra-operative Neurological											<u> </u>
Pediatric		1					1	· · · ·			
Small Organ (Specify) *		N	N	N		N	N	N	N	N	
Neonatal	l										
Cephalic			<u> </u>								
Adult Cephalic		ļ									
Cardiac	<u> </u>		<u> </u>						-		<u> </u>
Transesophageal					·						
Transrectal			L								<u> </u>
Transvaginal		<u> </u>		· · · · · · · · · · · · · · · · · · ·							
Transurethral		<u> </u>				• • • • • • • • • • • • • • • • • • •				·	
Intravascular											
Peripheral Vascular		N	N	N		N	N	N	<u>N</u>	N	ļ
Laparoscopic										· ·	ļ
Musculo-skeletal Conventional		N	N	N		N	N	N	N	N	
Musculo-skeletal Superficial		N	N	N		N	N	N	N	N	
Others (Specify)											

Mode of Operation

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)

(Division Sign-Off) Division of Reproductive, Abdominal, and Radiological Devices <0616-510(k) Number

Prescription Use (Per 21 CFR 801.109)

Ultrasound Device Indications Statement Page 4 of 20.

510(k) Number (if known) : <u>C061637</u>. Device Name : <u>Diagnostic Ultrasound System SDU-2200Pro, L040-120HU</u>

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:

Clinical Application	٨	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)**	Tissue Harmonic Imaging	Other (Specify)
Ophthalmic											
Fetal										· · · · · · · · · · · · · · · · · · ·	1
Abdominal							1				1
Intra-operative									_		
(Specify)											
Intra-operative											
Neurological	ł										
Pediatric		1									
Small Organ											
(Specify) *		N	N	N		N	N	N	N	N	
Neonatal		1	1				1				+
Cephalic											
Adult Cephalic											
Cardiac	1						1				
Transesophageal	1	1					1				
Transrectal											
Transvaginal											
Transurethral										· · · ·	
Intravascular								•			
Peripheral Vascular		N	N	N		N	N	N	N	N	
Laparoscopic								<u>``</u>	<u> </u>		1
Musculo-skeletal		N	N	N		N .	N	N	N	N.	
Conventional				••							
Musculo-skeletal Superficial		N	N	N		N	N	N	N	N	
Others (Specify)											

Mode of Operation

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 _____ K \$6/\$77

Ultrasound Device Indications Statement Page <u>5</u> of <u>20</u>.

< 061 510(k) Number (if known) : 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:

Clinical Application	A	B	М	PWD	CWD	Color Doppl e r	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)**	Tissue Harmonic Imaging	Other (Specify)
Ophthalmic											
Fetal											
Abdominal							1				1
Intra-operative							1	[
(Specify)											
Intra-operative		I						· · · · ·			
Neurological							1				
Pediatric							1	1			1
Small Organ		N.T.		<u>.</u>				, , , , , , , , , , , , , , , , , , ,			<u>†</u>
(Specify) *		N	N	N		N	N	N	N	N	
Neonatal								<u> </u>	1		1
Cephalic											
Adult Cephalic							-		1		
Cardiac		l					1	İ	1		1
Transesophageal											
Transrectal											1
Transvaginal							1				1
Transurethral							1				
Intravascular											1
Peripheral Vascular		N	N	N		N	N	N	N	N	<u> </u>
Laparoscopic						-			1		
Musculo-skeletal		N	Ν	N		N	N	N	N	N	1
Conventional											
Musculo-skeletal Superficial		N	Ν	N		N	N	N	N	N	
Others (Specify)						- ·					

Mode of Operation

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)

L

(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)

Ultrasound Device Indications Statement Page <u>6</u> of <u>20</u>.

510(k) Number (if known) : ____ K061631 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:

Clinical Application	٨	B	м	PWD	CWD	Color Doppl er	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)**	Tissue Harmonic Imaging	Other (Specify)
Ophthalm ic											
Fetal											
Abdominal									1		
Intra-operative							1				-
(Specify)		i									
Intra-operative	ſ										
Neurological											
Pediatric											1
Small Organ		N	N	N		N	N				
(Specify) *		N	Ν	N		N	N	N	N	N	
Neonatal							1				
Cephalic		ļ		:							ļ
Adult Cephalic									•		
Cardiac		I									1
Transesophageal											1
Transrectal											
Transvaginal		1									
Transurethral											
Intravascular										1	
Peripheral Vascular		Ν	N	N		N	N	N	N	N	
Laparoscopic							1				
Musculo-skeletal		Ν	N	N		N	N	N	N	N	1
Conventional				-		_					
Musculo-skeletal							1		-		1
Superficial											
Others (Specify)							1		-		1

Mode of Operation

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 (06/637

510(k) Number_

Ultrasound Device Indications Statement Page 7 of 20.

510(k) Number (if known) : <u>K061637</u> Device Name : <u>Diagnostic Ultrasound System SDU-2200Pro, VA11R-055U</u>

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:

Clinical Application	A	B	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)**	Tissue Harmonic Imaging	Other (Specify)
Ophthalmic							1	<u>₽</u>	1	<u>-</u>	+
Fetal		N	N	N		N	N	N	N	N	<u> </u>
Abdominal		N	N	N		N	N	<u>N</u>	N	N	
Intra-operative							1				<u>†</u> ∙
(Specify)											
Intra-operative								· · · · · · · · · · · · · · · · · · ·			+
Neurological											
Pediatric		N	N	N		N	N	N	N	N	+
Small Organ											<u> </u>
(Specify) *											
Neonatal		Ν	N	N		N	N	N	N	N	
Cephalic							1				
Adult Cephalic		N	N	N		N	N	N	N	N	
Cardiac		N	Ν	N		Ν	N	N	N	N	1
Transesophageal											
Transrectal										-	
Transvaginal											
Transurethral											+
Intravascular								··			
Peripheral Vascular							· · ·		+	····	-
Laparoscopic	-								<u> </u>	· · · · · ·	+
Musculo-skeletal								•• •• •			}
Conventional	Í		[
Musculo-skeletal									1		· · ·
Superficial					[
Others (Specifv)											<u> </u>

Mode of Operation

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)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED) Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ V (Per 21 CFR 801.109)

(Division Sign-Off)

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:

Clinical Application	٨	B	М	PWD	CWD	Calor Doppl e r	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)**	Tissue Harmonic Imaging	Other (Specify)
Ophthalmic							1				† ——···
Fetal		N	N	N		N	N	N	N	N	1
Abdominal		N	N	N		N	N	N	N	N	1
Intra-operative					-				1		<u> </u>
(Specify)											
Intra-operative									1		
Neurological											
Pediatric							1			i	1
Small Organ	l i										1
(Specify) *											
Neonatal											
Cephalic											
Adult Cephalic											1
Cardiac		N	Ν	N		N	N	N	- N	N	
Transesophageal											
Transrectal							1	-			<u> </u>
Transvaginal											
Transurethral											<u>+</u>
Intravascular							-		+		
Peripheral Vascular											
Laparoscopic											+
Musculo-skeletal											
Conventional											
Musculo-skeletal									+		
Superficial											
Others (Specify)							— · ·		1		·

Mode of Operation

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)

(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)

madar (Division Sign-Off) Division of Reproductive, Abdominal, and Radiological Devices and Radiological Devices Kobild 37

Ultrasound Device Indications Statement Page 9 of 20.

510(k) Number (if known) : _____ K 061637 Device Name : <u>Diagnostic Ultrasound System SDU-2200Pro, VA13R-050U</u>

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:

Clinical Application	٨	B	м	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)**	Tissue Harmonic Imaging	Other (Specify)
Ophthalmic											
Fetal		Ν	N	N		N	N	N	N	N	1
Abdominal		N	N	N		N	N	N	N	N	1
Intra-operative	ļ										1
(Specify)	ł										}
Intra-operative		[1				1
Neurological											
Pediatric		[1				1
Small Organ							ł				1
(Specify) *											
Neonatal							l l				
Cephalic					i		1				
Adult Cephalic											
Cardiac		N	N	Ν		N	N	N	N	N	
Transesophageal							1				
Transrectal							1				
Transvaginal							l				
Transurethral										•	
Intravascular							1				
Peripheral Vascular											•
Laparoscopic										1.	1
Musculo-skeletal											1
Conventional											
Musculo-skeletal									1	1	
Superficial									1		
Others (Specify)									1		1

Mode of Operation

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)

(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 064631

ł

Ultrasound Device Indications Statement Page <u>10</u> of <u>20</u>.

510(k) Number (if known) : <u>14061637</u>

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:

Clinical Application	٨	B	М	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	1
Intra-operative											
(Specify)											
Intra-operative											1
Neurological		ł						1			
Pediatric											1
Small Organ								i			1
(Specify) *											
Neonatal							j	1			
Cephalic											
Adult Cephalic	ŀ							İ			
Cardiac		N	Ν	N		N	N	N	N	N	
Transesophageal							1				1
Transrectal											
Transvaginal							Ì				1
Transurethral							1		- 1 · · · · ·		1
Intravascular							1				
Peripheral Vascular											
Laparoscopic					·						1
Musculo-skeletal											•
Conventional							·				
Musculo-skeletal								1			1
Superficial											
Others (Specify)											

Mode of Operation

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)

(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 637

.

Ultrasound Device Indications Statement Page <u>11</u> of <u>20</u>.

510(k) Number (if known) : <u>K061637</u> Device Name : <u>Diagnostic Ultrasound System SDU-2200Pro, VA40R-035U</u>

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:

Ophihalmic Imaging Imaging Fetal N	linical / pplication	٨	B	м	PWD	CWD	Color Doppler	Power (Amplitude)	Color Velocity	Combined (Specify)**	Tissue Harmonic	Other (Specify)
FetalNNNNNNNNNAbdominalNNNNNNNNNNNIntra-operative (Specify)<		_						Doppler	Imaging		Imaging	
Abdominal N		\rightarrow		<u>.</u>								
Intra-operative Intra-operative Intra-operative Intra-operative Intra-operative Intra-operative Neurological Intra-operative Intra-operative Pediatric Intra-operative Intra-operative Small Organ Intra-operative Intra-operative Small Organ Intra-operative Intra-operative Small Organ Intra-operative Intra-operative Neonatal Intra-operative Intra-operative Cephalic Intra-operative Intra-operative Adult Cephalic Intraseophageal Intraseophageal Transrectal Intravascular Intravascular Intravascular Intravascular Intravascular Intravascular Intravascular Intravascular Musculo-skeletal Intravascular Intravascular Intravascular Intravascular Intravascular <			4									<u> </u>
(Specify)IIIIIntra-operative NeurologicalIIIIPediatricIIIIISmall Organ (Specify) *IIIIINeonatal CephalicIIIIIAdult Cephalic CardiacIIIIITransesophageal TransvaginalIIIIITransvaginal Peripheral VascularIIIIILaparoscopic ConventionalIIIIIMusculo-skeletal ConventionalIIIII			N	N	N		N	<u> </u>	N	N	N	<u> </u>
Intra-operative Neurological Image: state		ĺ										
Neurological Image: state in the stat		_			<u> </u>			ļ				
PediatricImage: state in the sta											1	
Small Organ (Specify) *Image: Specify and Specify		\rightarrow							. <u> </u>			
(Specify)*Image: Specify and												
Neonatal CephalicImage: Second secon		ļ										
CephalicImage: CephalicImage: CephalicImage: CephalicImage: CephalicAdult CephalicImage: Certain ComparisonImage: Certain ComparisonImage: Certain ComparisonImage: Certain ComparisonCardiacImage: Certain ComparisonImage: Certain ComparisonImage: Certain ComparisonImage: Certain ComparisonImage: Certain ComparisonTransverationImage: Certain ComparisonImage: Certain ComparisonImage: Certain ComparisonImage: Certain ComparisonImage: Certain ComparisonToransure Certain ComparisonImage: Certain ComparisonImage: Certain ComparisonImage: Certain ComparisonImage: Certain ComparisonImage: Certain ComparisonImage: Certain ComparisonImage: Certain ComparisonImage: Certain ComparisonImage: Certain ComparisonImage: Certain ComparisonImage: Certain ComparisonImage: Certain ComparisonImage: Certain ComparisonImage: Certain Ce												
Adult CephalicImage: CardiacImage:								1		1		
CardiacImage: CardiacImage: CardiacImage: CardiacImage: CardiacTransesophagealImage: CardiacImage: CardiacImage: CardiacImage: CardiacTransrectalImage: CardiacImage: CardiacImage: CardiacImage: CardiacTransurethralImage: CardiacImage: CardiacImage: CardiacImage: CardiacIntravascularImage: CardiacImage: CardiacImage: CardiacImage: CardiacPeripheral VascularImage: CardiacImage: CardiacImage: CardiacImage: CardiacMusculo-skeletalImage: CardiacImage: CardiacImage: CardiacImage: CardiacConventionalImage: CardiacImage: CardiacImage: CardiacImage: Cardiac												
Transesophageal Image: Conventional	dult Cephalic											
Transrectal Image: Conventional	ardiac										-	1
Transvaginal Image: Conventional	·ansesophageal	T						1		1		
Transurethral Image: Conventional	ansrectal											
Intravascular Image: Conventional	ransvaginal							1				1
Peripheral Vascular Image: Conventional Image: Conventio	ansurethral				<u>_</u>			1				
Laparoscopic Image: Conventional	travascular	1										
Laparoscopic Image: Conventional	ripheral Vascular							1				
Musculo-skeletal Conventional		+			~ ~			1		+		
Conventional		\neg								+	· · ·	<u> </u>
Musculo-skeletal												
	usculo-skeletal	-+								·		
Superficial												
Others (Specify)		-+		-								+

Mode of Operation

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)

(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, Abdominai, and Radiological Devices 510(k) Number K06/637

Ultrasound Device Indications Statement Page <u>12</u> of <u>20</u>.

X06163 510(k) Number (if known) :

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:

Clinical Application	A	B	м	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		1									
Cardiac			1					1		1	1
Transesophageal											
Transrectal		1									
Transvaginal			i								
Transurethral		[1
Intravascular		1									
Peripheral Vascular											
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial							· · · ·				<u> </u>
Others (Specify)											

Mode of Operation

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)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED) Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ^{Der} 21 CFR 801.109)

(Division Sign-Off) Division of Reproductive, Abdominal, and Radiological Devices 510(k) Number ______K661631

Prescription Use (Per 21 CFR 801.109) Ultrasound Device Indications Statement Page <u>13</u> of <u>20</u>.

510(k) Number (if known) : _____ K 06163 4 Device Name : <u>Diagnostic Ultrasound System SDU-2200Pro, VA57R-0375WU</u>

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:

Clinical Application	٨	B	м	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)**	Tissue Harmonic Imaging	Other (Specify)
Ophthalmic					1						
Fetal		N	N	N		N	N	N	N	N	1
Abdominal		N	N	N		N	N	N	N	N	
Intra-operative								i			
(Specify)											
Intra-operative		Ī								·	1
Neurological			[
Pediatric		1								,	
Small Organ		1					1				
(Specify) *											
Neonatal		1						· · · · ·			
Cephalic											
Adult Cephalic											
Cardiac											1
Transesophageal							1				
Transrectal	1	1					İ				
Transvaginal											1
Transurethral	· · · ·						1				
Intravascular	1										1
Peripheral Vascular											
Laparoscopic											· · ·
Musculo-skeletal							+				
Conventional											
Musculo-skeletal Superficial											
Others (Specify)											

Mode of Operation

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)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED) Concurrence of CDRH, Office of Device Evaluation (ODE)

44-4-11

Prescription Use _ (Per 21 CFR 801.109)

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

.

Ultrasound Device Indications Statement Page <u>14</u> of <u>20</u>.

510(k) Number (if known) : <u>KO61637</u>. Device Name : <u>Diagnostic Ultrasound System SDU-2200Pro, VA57R-0375HU</u>

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:

Clinical Application	A	B	м	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)**	Tissue Harmonic Imaging	Other (Specify)
Ophthalmic											
Fetal		Ν	N	N		N	N	N	N	N	1 .
Abdominal		N	N	N	1	N	N	N	N	N	
Intra-operative											
(Specify)											
Intra-operative											
<u>Neurol</u> ogical							1				
Pediatric											1
Small Organ											1
(Specify) *									1		
Neonatal		[1
Cephalic]			· · · ·		1		1		
Adult Cephalic											
Cardiac											
Transesophageal	ĺ										
Transrectal							1				
Transvaginal	<u> </u>								1		
Transurethral											
Intravascular	1						1				
Peripheral Vascular	<u> </u>						1				1
Laparoscopic							1				1
Musculo-skeletal											
Conventional											
Musculo-skeletal Superficial									1		
Others (Specify)											

Mode of Operation

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)

(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 Prescription Use (Per 21 CFR 801.109) Ultrasound Device Indications Statement Page <u>15</u> of <u>20</u>.

510(k) Number (if known) : <u>K06163</u> Device Name : <u>Diagnostic Ultrasound System SDU-2200Pro, TV11R-055U</u>

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:

Clinical Application	Å	B	М	PWD	CWD	Color Doppl er	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)**	Tissue Harmonic Imaging	Other (Specify)
Ophthalmic											
Fetal		N	N	N		N	N	N	N	N	1
Abdominal							1				1
Intra-operative (Specify)											
Intra-operative Neurological											
Pediatric			1				1				1
Small Organ (Specify) *											-
Neonatal Cephalic											
Adult Cephalic		•									1
Cardiac							1				
Transesophageal	1							· · · · ·			
Transrectal		N	N	N		N	N	N	N	N	
Transvaginal		N	N	N		N	N	N	N	N	
Transurethral							1				
Intravascular						******					1
Peripheral Vascular											
Laparoscopic									1		+
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											1
Others (Specify)							1			1	1

Mode of Operation

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)

(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) A A Division of Reproductive, Abdominai, and Radiological Devices 510(k) Number 2006 (097

Ultrasound Device Indications Statement Page <u>16</u> of <u>20</u>.

510(k) Number (if known) : $1 \le 061637$

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:

Clinical Application	٨	B	м	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)**	Tissue Harmonic Imaging	Other (Specify)
Ophthalmic											
Fetal								1		1	1
Abdominal											
Intra-operative											
(Specify)											
Intra-operative											
Neurological							1				
Pediatric										· · · ·	1
Small Organ											
(Specify) *											
Neonatal									1		
Cephalic											
Adult Cephalic							ĺ				
Cardiac											
Transesophageal											
Transrectal		Ν	N	N		N	N	N	N	N	
Transvaginal										· · · ·	
Transurethral									1		
Intravascular									1		
Peripheral Vascular		-				· · · · · · · · · · · · · · · · · · · 	1		1		
Laparoscopic					•				1	i .	1
Musculo-skeletal						· ····································			1	-	
Conventional				1							
Musculo-skeletal									1	1	
Superficial											
Others (Specify)											

Mode of Operation

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)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED) Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of Reproductive, Abdomination and Radiological Devices 510(k) Number K & 16 37

Prescription Use (Per 21 CFR 801.109)

Ultrasound Device Indications Statement Page <u>17</u> of <u>20</u>.

510(k) Number (if known) : <u>1 × 061637</u> Device Name : <u>Diagnostic Ultrasound System SDU-2200Pro, EC11R-055U</u>

ŧ

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:

Clinical Application	٨	B	М	₽₩D	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)**	Tissue Harmonic Imaging	Other (Specify)
Ophthalmic										""	1
Fetal		N	N	N		N	N	N	N	N	1
Abdominal											
Intra-operative							1	1			1
(Specify)			ļ								
Intra-operative							1				
Neurological									1		
Pediatric											
Small Organ	I										
(Specify) *								•			İ
Neonatal							1				
Cephalic							•				
Adult Cephalic										-	
Cardiac	[1		
Transesophageal										· · · · ·	
Transrectal		N	N	N		N	N	N	N	N	
Transvaginal		Ν	N	N		N	N	N	N	N	
Transurethral											
Intravascular									1		
Peripheral Vascular		Ī						ĺ			1
Laparoscopic							1		1		
Musculo-skeletal					•••	·		·	-1	· ·	
Conventional								1			
Musculo-skeletal					·····		1		1		1
Superficial											
Others (Specify)							1	1			-†

Mode of Operation

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)

(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)

Jan Cheriden

(Division Sign-Off) Division of Reproductive, Abdominal, and Radiological Devices 510(k) Sumber_____KU61637____

Ultrasound Device Indications Statement Page <u>18</u> of 20 .

510(k) Number (if known) : <u>K06163</u> Device Name : Diagnostic Ultrasound Sy 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:

	1	<u> </u>		0.00		le of Oper	T		1 2 1 1	<u> </u>	
Clinical Application	1	B	м	₽₩D	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		Ν	N	N	N	N	N	N	N	N	+
Small Organ (Specify) *											
Neonatal		ĺ									
Cephalic									_		
Adult Cephalic											
Cardiac	•	Ν	N	N	Ň	N	N	N	N	N	
Transesophageal							•				1
Transrectal											
Transvaginal											1
Transurethral							1				
Intravascular							1			1	
Peripheral Vascular							1		1		
Laparoscopic							1				
Musculo-skeletal											
Conventional										1	
Musculo-skeletal Superficial											
Others (Specify)	_										1

Mode of Operation

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

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED) Concurrence of CDRH, Office of Device Evaluation (ODE)

Trascription Use

(Division Sign-Off)

Division of Reproductive, Abdominal, and Radiological Devices <0u1637

510(k) Number

Ultrasound Device Indications Statement Page <u>19</u> of <u>20</u>.

510(k) Number (if known) : <u>KOGI637</u> Device Name : <u>Diagnostic Ultrasound System SDU-2200Pro, S017-035U</u>

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:

Clinical Application	A	B	м	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										-	1
Adult Cephalic		1							1		
Cardiac		N	N	N	N	N	N	N	N	N	
Transesophageal			1				1				1
Transrectal		•					1				
Transvaginal											<u>+</u>
Transurethral											1
Intravascular									1	1	
Peripheral Vascular											
Laparoscopic										· .	
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Others (Specify)											

Mode of Operation

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

> (PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED) Concurrence of CDRH, Office of Device Evaluation (ODE)

Lucií (

(Division Sign-Off) Division of Reproductive, Abdominal, and Radiological Devices 510(k) Number 526/637

Prescription Use (Per 21 CFR 801.109)

Ultrasound Device Indications Statement Page 20 of 20 .

K06163 510(k) Number (if known) : _ Device Name : Diagnostic Ultrasound System 200Pro, 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:

Clinical Application	A	B	M	₽₩D	CWD	Color	Power	Color	Combined	Tissue	Other
						Doppler	(Amplitude) Doppler	Velocity Imaging	(Specify)**	Harmonic Imaging	(Specify)
Ophthalmic											
Fetal											
Abdominal				N		N	N			N	
Intra-operative (Specify)											
Intra-operative Neurological											
Pediatric			I								
Small Organ (Specify) *											
Neonatal Cephalic			·								
Adult Cephalic	<u>†</u>	1								-	+
Cardiac		N	N	Ň	N	N	N	N	N	N	
Transesophageal			<u>+</u>		<u> </u>						
Transrectal		1					1			†	1
Transvaginal	1		•		·						
Transurethral	1	1						1	-		1
Intravascular	1										
Peripheral Vascular		1			1	1					
Laparoscopic		1									
Musculo-skeletal					[
Conventional											
Musculo-skeletal Superficial											
Others (Specify)											

Mode of Operation

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

> (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)

72-7 (Division Sign-Off)

Division of Reproductive, Abdominal.

Division of Reproduction and Radiological Devices 637