K082224

DEC 15 2008

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: Don Karle

1.3 Date: July 23, 2008

2.0 DEVICE NAME

2.1 Proprietary Name: sarano

2.2 Common Name: Ultrasound Imaging System

2.3 Classification: 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 Corporation sarano (K061641, Jul 14. 2006)

3.0 DEVICE DESCRIPTION

The sarano is a mobile diagnostic ultrasound system. This system has flat linear array, convex and with a frequency range of approximately 2 to 15 MHz. It has B mode, M mode, or in a combination of modes.
Also the sarano has two kinds of monitor; CRT and LCD. The former is standard model and latter is optional model.

4.0 INTENDED USE

The sarano 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

The sarano 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

Mr. Don Karle
Customer Service Manager
Shimadzu Medical Systems
20101 South Vermont Avenue
TORRANCE CA 90502-1328

DEC 15 2008

Re: K082224
Trade/Device Name: Diagnostic Ultrasound System sarano, system
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: IYO and ITX
Dated: July 23, 2008
Received: September 22, 2008

Dear Mr. Karle:

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 sarano, system, as described in your premarket notification:

Transducer Model Number

L040-120HU	VA40R-035U	L072-050U
L040-100U	VA57R-0375WU	VA20R-035U
L070-075U	TV11R-055U	VA57R-0375U
VA11R-055U	EC11R-055U	VA57R-0375SU
VA13R-035U	UB10R-065U	

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.

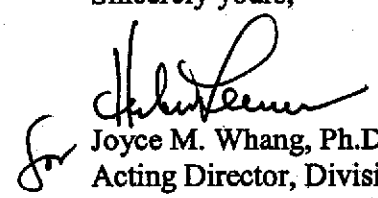
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 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 Paul Hardy at (240) 276-3666.

Sincerely yours,



for Joyce M. Whang, Ph.D.
Acting 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 15 .

510(k) Number (if known) : K082224

Device Name : Diagnostic Ultrasound System sarano, 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		P	P						P	P	
Abdominal		P	P						P	P	
Intra-operative (Specify)											
Intra-operative Neurological											
Pediatric											
*Small Organ (Specify) **		P	P						P	P	
Neonatal Cephalic		N	N						N	N	
Adult Cephalic											
Cardiac		P	P						P	P	
Transesophageal											
Transrectal		P	P						P	P	
Transvaginal		P	P						P	P	
Transurethral											
Intravascular											
Peripheral Vascular		P	P						P	P	
Laparoscopic											
Musculo-skeletal Conventional		P	P						P	P	
Musculo-skeletal Superficial		P	P						P	P	
Other (Specify)											

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

Other Indications or Modes:

* Thyroid, Testicles, Breast

** B/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 K082224

Prescription Use ✓
(Per 21 CFR 801.109)

Prescription Use (Per 21 CFR 801.109)

Ultrasound Device Indications Statement Page 2 of 15 .

510(k) Number (if known) : K061641 .

Device Name : Diagnostic Ultrasound System sarano, 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) **		P	P						P	P	
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular		P	P						P	P	
Laparoscopic											
Musculo-skeletal Conventional		P	P						P	P	
Musculo-skeletal Superficial		P	P						P	P	
Others (Specify)											

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

Other Indications or Modes:

* Thyroid, Testicles, Breast

** B/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 K082224

Prescription Use ✓
(Per 21 CFR 801.109)

Prescription Use (Per 21 CFR 801.109)

Ultrasound Device Indications Statement Page 3 of 15 .

510(k) Number (if known) : K061641 .

Device Name : Diagnostic Ultrasound System sarano, L040-100U

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) **		P	P						P	P	
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular		P	P						P	P	
Laparoscopic											
Musculo-skeletal Conventional		P	P						P	P	
Musculo-skeletal Superficial		P	P						P	P	
Other (Specify)											

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

Other Indications or Modes:

* Thyroid, Testicles, Breast

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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 K082224

Prescription Use ✓
(Per 21 CFR 801.109)

Prescription Use (Per 21 CFR 801.109)

Ultrasound Device Indications Statement

510(k) Number (if known) : K061641 .
Device Name : Diagnostic Ultrasound System sarano, 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) **		P	P						P	P	
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular		P	P						P	P	
Laparoscopic											
Musculo-skeletal Conventional		P	P						P	P	
Musculo-skeletal Superficial		P	P						P	P	
Others (Specify)											

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

Other Indications or Modes:
* Thyroid, Testicles, Breast
** B/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 K082224

Prescription Use (Per 21 CFR 801.109)

Ultrasound Device Indications Statement Page 5 of 15 .

510(k) Number (if known) :

Device Name : Diagnostic Ultrasound System sarano, 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		P	P						P	P	
Abdominal		P	P						P	P	
Intra-operative (Specify)											
Intra-operative Neurological											
Pediatric											
*Small Organ (Specify) **											
Neonatal Cephalic		N	N						N	N	
Adult Cephalic											
Cardiac		P	P						P	P	
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

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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 K082224

Prescription Use (Per 21 CFR 801.109)

Ultrasound Device Indications Statement Page 6 of 15 .

510(k) Number (if known) : K061641.

Device Name : Diagnostic Ultrasound System sarano, 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		P	P						P	P	
Abdominal		P	P						P	P	
Intra-operative (Specify)											
Intra-operative Neurological											
Pediatric											
*Small Organ (Specify) **											
Neonatal Cephalic											
Adult Cephalic											
Cardiac		P	P						P	P	
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:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

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Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K082224

Prescription Use (Per 21 CFR 801.109)

Ultrasound Device Indications Statement Page 7 of 15 .

510(k) Number (if known) : K061641 .

Device Name : Diagnostic Ultrasound System sarano, 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		P	P						P	P	
Abdominal		P	P						P	P	
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

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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 K082224

Prescription Use ✓
(Per 21 CFR 801.109)

Prescription Use (Per 21 CFR 801.109)

Ultrasound Device Indications Statement Page 8 of 15 .

510(k) Number (if known) : K061641 .

Device Name : Diagnostic Ultrasound System sarano, 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		P	P						P	P	
Abdominal		P	P						P	P	
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)											

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Other Indications or Modes:

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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 K082224

Prescription Use (Per 21 CFR 801.109)

Ultrasound Device Indications Statement Page 9 of 15 .

510(k) Number (if known) : K061641 .

Device Name : Diagnostic Ultrasound System sarano, 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		P	P						P	P	
Abdominal											
Intra-operative (Specify)											
Intra-operative Neurological											
Pediatric											
*Small Organ (Specify) **											
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Transesophageal											
Transrectal		P	P						P	P	
Transvaginal		P	P						P	P	
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:

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Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K082224

Prescription Use ✓
(Per 21 CFR 801.109)

Prescription Use (Per 21 CFR 801.109)

Ultrasound Device Indications Statement Page 10 of 15 .

510(k) Number (if known) : K061641 .

Device Name : Diagnostic Ultrasound System sarano, 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		P	P						P	P	
Abdominal											
Intra-operative (Specify)											
Intra-operative Neurological											
Pediatric											
Small Organ (Specify) *											
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Transesophageal											
Transrectal		P	P						P	P	
Transvaginal		P	P						P	P	
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:

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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 K082224

Prescription Use ✓
(Per 21 CFR 801.109)

Prescription Use (Per 21 CFR 801.109)

Ultrasound Device Indications Statement Page 11 of 15 .

510(k) Number (if known) : K061641 .

Device Name : Diagnostic Ultrasound System sarano, 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		P	P						P	P	
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:

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Division of Reproductive, Abdominal and Radiological Devices

510(k) Number K082224

Prescription Use ✓

(Per 21 CFR 801.109)

Prescription Use (Per 21 CFR 801.109)

Ultrasound Device Indications Statement Page 12 of 15 .

510(k) Number (if known) : K061641 .

Device Name : Diagnostic Ultrasound System sarano, 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) **		P	P						P	P	
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular		P	P						P	P	
Laparoscopic											
Musculo-skeletal Conventional		P	P						P	P	
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

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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 K082724

Prescription Use ✓
(Per 21 CFR 801.109)

Prescription Use (Per 21 CFR 801.109)

Ultrasound Device Indications Statement Page 13 of 15 .

510(k) Number (if known) : K061641 .

Device Name : Diagnostic Ultrasound System sarano, 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		P	P						P	P	
Abdominal		P	P						P	P	
Intra-operative (Specify)											
Intra-operative Neurological											
Pediatric											
*Small Organ (Specify) **											
Neonatal Cephalic											
Adult Cephalic											
Cardiac		P	P						P	P	
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:

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Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K082224

Prescription Use (Per 21 CFR 801.109)

Ultrasound Device Indications Statement Page 14 of 15 .

510(k) Number (if known) : K061641 .

Device Name : Diagnostic Ultrasound System sarano, VA57R-0375U

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		P	P						P	P	
Abdominal		P	P						P	P	
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

(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 K082224

Prescription Use (Per 21 CFR 801.109)

Ultrasound Device Indications Statement Page 15 of 15 .

510(k) Number (if known) :

Device Name : Diagnostic Ultrasound System sarano, VA57R-0375SU

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	
Abdominal		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

(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 K082224