

OCT 28 1998

510(K) SUMMARY

K981528

**Addition of Contrast Agent Imaging to SONOLINE Elegra Diagnostic Ultrasound system**

This summary of safety and effectiveness is provided as part of this Premarket Notification in compliance with the Safe Medical Device Act of 1990 revisions to 21 CFR, Part 807.92, Content and Format of a 510(k) Summary. Contrast Agent Imaging (CAI) is a patented technique (US patent number 5,632,277).

1. **Submitted By:**

Siemens Medical Systems, Inc., Ultrasound Group  
22010 S.E. 51st Street  
Issaquah, WA 98027-7002

**Contact Person:**

Steve Hesler  
Manager of Regulatory Affairs  
(425) 557-1629

**Date Prepared:**

March 31, 1998

2. **Proprietary Name:**

SONOLINE Elegra Advanced  
SONOLINE Elegra

**Common/ Usual Name:**

Diagnostic Ultrasound System with Accessories

**Classification Name:**

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

3. **Predicate Device:**

- Acuson Sequoia™ Ultrasound System and Harmonic Imaging with Contrast Option (K973767, 12/23/97)
- SONOLINE Elegra (K945072, 11/21/95).

4. **Device Description:**

The SONOLINE Elegra is a general purpose, mobile, software-controlled, diagnostic ultrasound system with an on-screen display for thermal and mechanical indices related to potential bioeffect mechanisms. Its function is to acquire ultrasound data and display it in B-Mode, M-Mode, Color Mode, Pulsed (PW) Doppler Mode, Continuous (CW) Doppler Mode, or in a combination of modes, on a CRT display.

The SONOLINE ® Elegra, has been designed to meet the following product safety standards:

- UL 2601-1, Safety Requirements for Medical Equipment
- CSA 22.2 No. 601-1, Safety Requirements for Medical Equipment
- Standard for Real Time Display of Thermal and Mechanical Indices on Diagnostic Ultrasound Equipment, AIUM/NEMA, 1992.

- 93/42/EEC Medical Devices Directive  
EN60601 = (IEC 601-1+ IEC 601-1-2), Safety and EMC Requirements for  
Medical Equipment

**5. Intended Uses:**

The SONOLINE Elegra ultrasound imaging system is intended for the following applications: General Radiology, Abdominal, Intraoperative, Small Parts, Transcranial, OB/GYN, Pelvic, Neonatal/Adult Cephalic, Urology, Vascular, Musculoskeletal, Superficial Musculoskeletal, and Peripheral Vascular applications. The addition of contrast agent imaging will not add any new applications or intended uses.

The system also provides for the measurement of anatomical structures and for analysis packages that provide information that is used for clinical diagnosis purposes.

**6. Technological Comparison to Predicate Device:**

Both the SONOLINE Elegra and the predicate device from Acuson are full-featured, high-end diagnostic ultrasound systems capable of B-mode, M-mode, CW Doppler, Color Doppler, Amplitude Doppler, and combined imaging modes utilizing a number of transducers with varying center frequencies.

Both systems are modified to optimize images obtained with the use of diagnostic ultrasound and ultrasound contrast agents.

Both systems employ modified transmit/receive functions which allow for enhanced imaging of tissues and structures which reflect the transmitted ultrasound at a harmonic, or multiple, of the transmit frequency.

**End of 510(k) Summary**



OCT 28 1998

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Steve Hesler  
Manager of Regulatory Affairs  
Siemens Medical Systems, Inc.  
Ultrasound Group  
22010 S.E. 51<sup>st</sup> St.  
Issaquah, WA 98029-7002

Re: K981528  
Trade Name: Sonoline Elegra and Elegra Advanced Diagnostic  
Ultrasound System (with Harmonic Imaging)  
Regulatory Class: II  
Product Code: 90 IYO/21 CFR 892.1560  
Dated: October 7, 1998  
Received: October 9, 1998

Dear Mr. Hesler:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following probes intended for use with the Sonoline Elegra and Elegra Advanced Diagnostic Ultrasound System, as described in your premarket notification:

Probes Model Number

2.5PL20 Phased Array  
3.5PL28 Phased Array  
3.5C40 Curved Array  
5.0HDPL40 Linear Array  
5.0C50 Curved Array  
6.5EC10 Curved Array  
6.5EV13 Curved Array  
7.5C30 Curved Array  
7.5L40 Linear Array  
7.5PL13 Phased Array

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic QS inspections, the FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification does not affect any obligation you may have under sections 531 and 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Please be advised that the determination above is based on the fact that no medical devices have been demonstrated to be safe and effective for in vitro fertilization or percutaneous umbilical blood sampling, nor have any devices been marketed for these uses in interstate commerce prior to May 28, 1976, or reclassified into class I (General Controls) or class II (Special Controls). FDA considers devices specifically intended for in vitro fertilization and percutaneous umbilical blood sampling to be investigational, and subject to the provision of the investigational device exemptions (IDE) regulations, 21 CFR, Part 812. Therefore, your product labeling must be consistent with FDA's position on this use.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

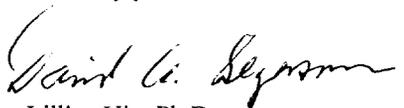
Food and Drug Administration  
Center for Devices and Radiological Health  
Document Mail Center (HFZ-401)  
9200 Corporate Boulevard  
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

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

Sincerely yours,

*for*   
Lillian Yin, Ph.D.  
Director, Division of Reproductive,  
Abdominal, Ear, Nose and Throat,  
and Radiological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosures

**Attachment 1**

**Ultrasound Device Indications Statement**

510 (k) Number (if known) : **K981528**  
 Device Name : **SONOLINE Elegra/Elegra Advanced**  
 Intended Use: See below

**Mode of Operation**

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging
Ophthalmic										
Fetal		P	P	P	P	P	P		BMDC (P)	N
Abdominal		P	P	P	P	P	P		BMDC (P)	N
Intraoperative (Specify) *		P	P	P	P	P	P		BMDC (P)	
Pediatric		P	P	P	P	P	P		BMDC (P)	N
Small Organ (Specify) **		P	P	P	P	P	P		BMDC (P)	N
Neonatal Cephalic		P	P	P	P	P	P		BMDC (P)	
Adult Cephalic		P	P	P	P	P	P		BMDC (P)	
Cardiac		P	P	P	P	P	P		BMDC (P)	N
Trans-esophageal										
Transrectal		P	P	P	P	P	P		BMDC (P)	
Transvaginal		P	P	P	P	P	P		BMDC (P)	N
Transurethral										
Intravascular										
Peripheral vessel		P	P	P	P	P	P		BMDC (P)	N
Laparoscopic										
Musculo-skeletal Conventional		P	P	P	P	P	P		BMDC (P)	N
Musculo-skeletal Superficial		P	P	P	P	P	P		BMDC (P)	N
Other (specify)										

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

Additional Comments:

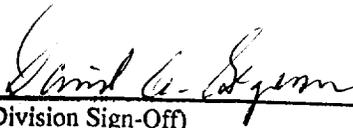
\* = intraoperative (abdominal, neurological)

\*\* = small organs (breast, testes, thyroid, penis, prostate)

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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, ENT,  
 and Radiological Devices  
 510(k) Number K981528

Ultrasound Device Indications Statement

510 (k) Number (if known) : **K981528**

Device Name : **2.0 CW probe for use with SONOLINE Elegra/Elegra Advanced**

Intended Use: See below

Mode of Operation

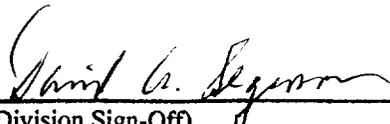
Clinical Application	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging
Ophthalmic										
Fetal					P					
Abdominal					P					
Intraoperative (Specify)					P					
Pediatric					P					
Small Organ (Specify)					P					
Neonatal Cephalic					P					
Adult Cephalic					P					
Cardiac					P					
Trans-esophageal										
Transrectal					P					
Transvaginal					P					
Transurethral										
Intravascular										
Peripheral vessel					P					
Laparoscopic										
Musculo-skeletal Conventional					P					
Musculo-skeletal Superficial										
Other (Specify)										

N = new Indication; P = previously cleared by FDA; E = added under Appendix E  
 Additional Comments: \_\_\_\_\_

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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, ENT,  
 and Radiological Devices  
 510(k) Number K981528

Ultrasound Device Indications Statement

510 (k) Number (if known) : **K981528**

Device Name : **2.5PL20 Phased Array Transducer for use with SONOLINE Elegra/Elegra Advanced**

Intended Use: See below.

Mode of Operation

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging
Ophthalmic										
Fetal		E	E	E	E	E	E		BMDC (E)	N
Abdominal		E	E	E	E	E	E		BMDC (E)	N
Intraoperative (Specify)										
Pediatric		E	E	E	E	E	E		BMDC (E)	N
Small Organ (Specify)										
Neonatal Cephalic		E	E	E	E	E	E		BMDC (E)	
Adult Cephalic		E	E	E	E	E	E		BMDC (E)	
Cardiac		E	E	E	E	E	E		BMDC (E)	N
Transesophageal										
Transrectal										
Transvaginal										N
Transurethral										
Intravascular										
Peripheral vessel		E	E	E	E	E	E		BMDC (E)	N
Laparoscopic										
Musculoskeletal Conventional										
Musculoskeletal Superficial										
Other (Specify)										

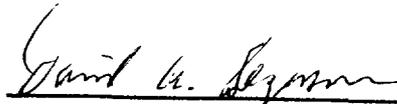
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Additional Comments:

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 Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

  
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 (Division Sign-Off)

Division of Reproductive, Abdominal, ENT,  
 and Radiological Devices

510(k) Number K981528

Ultrasound Device Indications Statement

510 (k) Number (if known) : **K981528**

Device Name : **3.5PL28 Phased Array Transducer for use with SONOLINE Elegra/Elegra Advanced**

Intended Use: See below.

Mode of Operation

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging
Ophthalmic										
Fetal		P	P	P	P	P	P		BMDC (P)	N
Abdominal		P	P	P	P	P	P		BMDC (P)	N
Intraoperative (Specify)										
Pediatric		P	P	P	P	P	P		BMDC (P)	N
Small Organ (Specify)										
Neonatal Cephalic		P	P	P	P	P	P		BMDC (P)	
Adult Cephalic		P	P	P	P	P	P		BMDC (P)	
Cardiac										
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		P	P	P	P	P	P		BMDC (P)	N
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (Specify)										

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

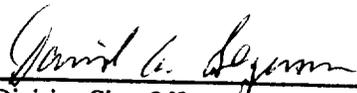
Additional Comments:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

  
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 (Division Sign-Off)  
 Division of Reproductive, Abdominal, ENT,  
 and Radiological Devices  
 510(k) Number K981528

Ultrasound Device Indications Statement

510 (k) Number (if known) : **K981528**

Device Name : **3.5C40 Curved Array Transducer for use with SONOLINE Elegra/Elegra Advanced**

Intended Use: See below

Mode of Operation

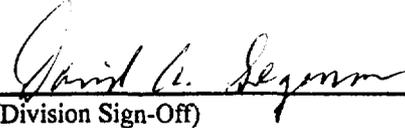
Clinical Application	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging
Ophthalmic										
Fetal		E	E	E		E	E		BMDC (E)	N
Abdominal		E	E	E		E	E		BMDC (E)	N
Intraoperative (Specify)										
Pediatric		E	E	E		E	E		BMDC (E)	N
Small Organ (Specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		E	E	E		E	E		BMDC (E)	N
Laparoscopic										
Musculo-skeletal Conventional		E	E	E		E	E		BMDC (E)	N
Musculo-skeletal Superficial										
Other (Specify)										

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

Additional Comments: \_\_\_\_\_

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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, ENT,  
 and Radiological Devices  
 510(k) Number K981528

Ultrasound Device Indications Statement

510 (k) Number (if known) : **K981528**

Device Name : **5.0HDPL40 Linear Array Transducer for use with SONOLINE Elegra/Elegra  
 Advanced**

Intended Use: See below

Mode of Operation

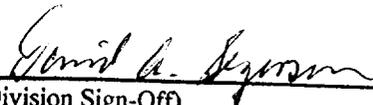
Clinical Application	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging
Ophthalmic										
Fetal		P	P	P		P	P		BMDC (P)	N
Abdominal		P	P	P		P	P		BMDC (P)	N
Intraoperative (Specify)										
Pediatric		P	P	P		P	P		BMDC (P)	N
Small Organ (Specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		P	P	P		P	P		BMDC (P)	N
Laparoscopic										
Musculo-skeletal Conventional		P	P	P		P	P		BMDC (P)	N
Musculo-skeletal Superficial										
Other (Specify)										

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

Additional Comments: \_\_\_\_\_  
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Prescription Use (Per 21 CFR 801.109)

  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal, ENT,  
 and Radiological Devices  
 510(k) Number K981528

Ultrasound Device Indications Statement

510 (k) Number (if known) : **K981528**

Device Name : **5.0C50 Curved Array Transducer for use with SONOLINE Elegra/Elegra Advanced**

Intended Use: See below

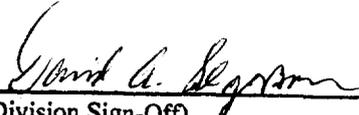
Mode of Operation

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging
Ophthalmic										
Fetal		P	P	P		P	P		BMDC (P)	N
Abdominal		P	P	P		P	P		BMDC (P)	N
Intraoperative (Specify)										
Pediatric		P	P	P		P	P		BMDC (P)	N
Small Organ (Specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		P	P	P		P	P		BMDC (P)	N
Laparoscopic										
Musculo-skeletal Conventional		P	P	P		P	P		BMDC (P)	N
Musculo-skeletal Superficial										
Other (Specify)										

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

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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, ENT,  
 and Radiological Devices  
 510(k) Number K981528

Ultrasound Device Indications Statement

510 (k) Number (if known) : **K981528**

Device Name : **6.5EC10 Curved Array Transducer for use with SONOLINE Elegra/Elegra Advanced**

Intended Use: See below

Mode of Operation

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Specify)										
Pediatric										
Small Organ (Specify) **		E	E	E		E	E		BMDC (E)	N
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal		E	E	E		E	E		BMDC (E)	
Transvaginal		E	E	E		E	E		BMDC (E)	N
Transurethral										
Intravascular										
Peripheral vessel										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (Specify)										

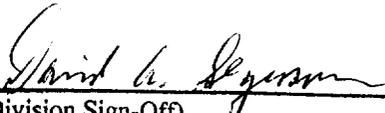
N = new indication; P = previously cleared by FDA; E = added under Appendix E

Additional Comments: \_\_\_\_\_

\*\* =small organ (breast, testes, thyroid, penis, prostate)

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Prescription Use (Per 21 CFR 801.109)

  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal, ENT,  
 and Radiological Devices  
 510(k) Number K981528

Ultrasound Device Indications Statement

510 (k) Number (if known) : **K981528**

Device Name : **6.5EV13 Curved Array Transducer for use with SONOLINE Elegra/Elegra Advanced**

Intended Use: See below

Mode of Operation

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Specify)										
Pediatric										
Small Organ (Specify) **		P	P	P		P	P		BMDC (P)	N
Neonatal Cephalic		P	P	P		P	P		BMDC (P)	
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal		P	P	P		P	P		BMDC (P)	
Transvaginal		P	P	P		P	P		BMDC (P)	N
Transurethral										
Intravascular										
Peripheral vessel										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (Specify)										

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

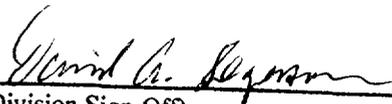
Additional Comments:

\*\* =small organ (breast, testes, thyroid, penis, prostate)

(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, ENT,  
 and Radiological Devices  
 510(k) Number K981528

Ultrasound Device Indications Statement

510 (k) Number (if known) : **K981528**

Device Name : **7.5C30 Curved Array Transducer for use with SONOLINE Elegra/Elegra Advanced**

Intended Use: See below

Mode of Operation

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging
Ophthalmic										
Fetal		E	E	E		E	E		BMDC (E)	N
Abdominal		E	E	E		E	E		BMDC (E)	N
Intraoperative (Specify)										
Pediatric		E	E	E		E	E		BMDC (E)	N
Small Organ (Specify) **		E	E	E		E	E		BMDC (E)	N
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		E	E	E		E	E		BMDC (E)	N
Laparoscopic										
Musculo-skeletal Conventional		E	E	E		E	E		BMDC (E)	N
Musculo-skeletal Superficial										
Other (Specify)										

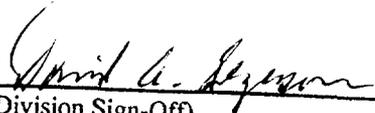
N = new indication; P = previously cleared by FDA; E = added under Appendix E

Additional Comments:

\*\* =small organ (breast, testes, thyroid, penis)

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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, ENT,  
 and Radiological Devices  
 510(k) Number K981528

Ultrasound Device Indications Statement

510 (k) Number (if known) : **K981528**

Device Name : **7.5L40 Linear Array Transducer for use with SONOLINE Elegra/Elegra Advanced**

Intended Use: See below

Mode of Operation

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging
Ophthalmic										
Fetal		P	P	P		P	P		BMDC (P)	N
Abdominal		P	P	P		P	P		BMDC (P)	N
Intraoperative (Specify) *		P	P	P		P	P		BMDC (P)	
Pediatric		P	P	P		P	P		BMDC (P)	N
Small Organ (Specify) **		P	P	P		P	P		BMDC (P)	N
Neonatal Cephalic		P	P	P		P	P		BMDC (P)	
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		P	P	P		P	P		BMDC (P)	N
Laparoscopic										
Musculo-skeletal Conventional		P	P	P		P	P		BMDC (P)	N
Musculo-skeletal Superficial		P	P	P		P	P		BMDC (P)	N
Other (Specify)										

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

Additional Comments:

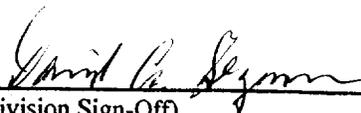
\* = intraoperative (abdominal, neurological)

\*\* =small organ (breast, testes, thyroid, penis)

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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, ENT,  
 and Radiological Devices  
 510(k) Number K981528

Ultrasound Device Indications Statement

510 (k) Number (if known) : **K981528**

Device Name : **7.5PL13 Phased Array Transducer for use with SONOLINE Elegra/Elegra Advanced**

Intended Use: See below

Mode of Operation

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging
Ophthalmic										
Fetal		E	E	E	E	E	E		BMDC (E)	N
Abdominal		E	E	E	E	E	E		BMDC (E)	N
Intraoperative (Specify)										
Pediatric		E	E	E	E	E	E		BMDC (E)	N
Small Organ (Specify) **		E	E	E	E	E	E		BMDC (E)	N
Neonatal Cephalic		E	E	E	E	E	E		BMDC (E)	
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		E	E	E	E	E	E		BMDC (E)	N
Laparoscopic										
Musculo-skeletal Conventional		E	E	E	E	E	E		BMDC (E)	N
Musculo-skeletal Superficial										
Other (Specify)										

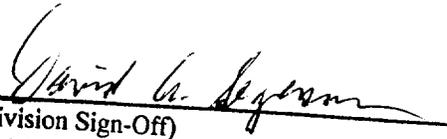
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Additional Comments:

\*\* = small organ (breast, testes, thyroid, penis)

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 510(k) Number K981528