K032114

510(k) SUMMARY

JUL 21 2003

Sequoia 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.

1. **Submitted By:**

Siemens Medical Solutions USA, Inc., Ultrasound Division
1230 Shorebird Way
PO Box 7393
Mt. View, California 94039-7393

Contact Person
Mr. Jerry W. Tsutsumi
Regulatory Affairs Department
Phone: (650) 943-7286
Fax: (650) 961-6168

Date Prepared
29 January 2003

2. **Proprietary Name:**
Sequoia Diagnostic Ultrasound System

Common/ Usual Name:
Diagnostic Ultrasound System with Accessories

Classification Name:
21 CFR 892.1550

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
Diagnostic Intravascular Catheter	FR # 870.1200	Product Code 90-DQO

3. **Predicate Device:**
K022567 (8/13/2002) cleared as Axius Edge Assisted Ejection Fraction, FreeStyle Extended Imaging and several new transducers (V7M TEE, 8L5T, 10V4, 13L5SP and 4V1c) for the Sequoia Diagnostic Ultrasound System Signature II.

4. **Device Description:**
The Sequoia 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 primary or secondary harmonic ultrasound echo data and display it in B-mode, M-mode, Pulsed (PW) Doppler mode, Continuous (CW) wave Doppler mode, color Doppler mode, Power Amplitude Doppler mode, a combination of these modes, Harmonic Imaging, or 3D imaging, on a CRT display.

The Sequoia diagnostic ultrasound system has been designed to conform to the following product safety standards:

- UL 2601-1, Safety Requirements for Medical Equipment
- CSA C22.2 No. 601-1, Safety Requirements for Medical Equipment
- AIUM/NEMA UD-2, 1998, Acoustic Output Measurement Standard for Diagnostic Ultrasound
- AIUM/NEMA UD-3, 1998, Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
- 93/42/EEC Medical Devices Directive
- Safety and EMC Requirements for Medical Equipment
- EN 60601-1
  - EN 60601-1-1
  - EN 60601-1-2
- IEC 1157 Declaration of Acoustic Power
- ISO 10993 Biocompatibility
- The systems acoustic output is in accordance with ALARA (as low as reasonably achievable) principle

5. Intended Uses:

The Sequoia diagnostic ultrasound system is intended for the following:

General Imaging and Cardiology for Fetal, Abdominal, Intraoperative (abdominal and neurological), Pediatrics, Small Organs (breast, testes, thyroid, penis and prostate), Neonatal/Adult Cephalic, Cardiac (adult, pediatric and neonatal), Trans-esophageal, Transrectal, Transvaginal, Peripheral Vessel, and Musculo-skeletal (superficial and conventional) applications, and intended uses as defined in the FDA guidance document.

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

6. Technological Comparison to Predicate Device:

The Sequoia is substantially equivalent in its technologies and functionality to the Sequoia Diagnostic Ultrasound System Signature II, that is already cleared for USA distribution under 510(k) premarket notification number K022567.

The Sequoia functions in the same manner as other diagnostic ultrasound systems, in that they transmit ultrasonic energy into the body via a transducer. In the body, acoustic impedance of different tissues reflect different amounts of ultrasound energy back to the transducer, where post processing of received echoes is performed to generate two-dimensional on-screen images of anatomic structures and fluid flow within the body. Doppler principles are used to process reflected ultrasound energy to display moving blood as a spectrum, or as color-coded two-dimensional images. All predicate devices listed above, allow for specialized measurements of structures and flow, and provide various calculations functions.

End of 510(k) Summary

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Siemens Medical Solutions USA, Inc.
% Ms. Laura Danielson
Responsible Third Party
510(k) Program Manager
TÜV Product Service
1775 Old Highway 8 NW, Suite 104
NEW BRIGHTON MN 55112-1891

JUL 21 2003

Re: K032114
Trade Name: Sequoia 8.0 Diagnostic Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: II
Product Code: 90 IYN, IYO, and ITX
Dated: July 8, 2003
Received: July 9, 2003

Dear Ms. Danielson:

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

This determination of substantial equivalence applies to the following transducers intended for use with the Sequoia 8.0 Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

4C1
5C2

6C2
8C4
EC10c5
EV8C4
6L3
AcuNav IC10V5/10F10 (Catheter)
8L5
8L5T
13L5SP
15L8
15L8w
V5M TEE
V7M TEE
V7B TEE
3V2c
4V1
4V1c (Sirius)
4V2
5V2c
7V3c
Gemini
8V5
10V4
AUX CW

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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

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

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

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

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

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

David A. Feigal

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

Enclosure(s)

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **Sequoia 8.0 Diagnostic Ultrasound System**

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

Clinical Application	Mode of Operation										
	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other : Harmonic Imaging	Other : 3D
Ophthalmic											
Fetal		P	P	P	P	P	P		P*	P	P
Abdominal		P	P	P	P	P	P		P*	P	P
Intraoperative Abdominal		P	P	P	P	P	P		P*	P	P
Intraoperative Neurological		P	P	P	P	P	P		P*	P	P
Pediatric		P	P	P	P	P	P		P*	P	P
Small Organ (Specify) **		P	P	P	P	P	P		P*	P	P
Neonatal Cephalic		P	P	P	P	P	P		P*	P	P
Adult Cephalic		P	P	P	P	P	P		P*	P	P
Cardiac		P	P	P	P	P	P		P*	P	P
Trans-esophageal		P	P	P	P	P	P		P*	P	P
Transrectal		P	P	P	P	P	P		P*	P	P
Transvaginal		P	P	P	P	P	P		P*	P	P
Transurethral											
Intravascular											
Peripheral vessel		P	P	P	P	P	P		P*	P	P
Laparoscopic											
Musculo-skeletal Conventional		P	P	P	P	P	P		P*	P	P
Musculo-skeletal Superficial		P	P	P	P	P	P		P*	P	P
Other (specify) ***		P	P	P	P	P	P		P*	P	P

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

Additional Comments:

*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+Color Doppler, B+CWD+Color Doppler, B+PWD+Color Doppler, B+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+M+Power Doppler

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

*** neonatal cardiac

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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 K032114

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: 4C1

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

Clinical Application	Mode of Operation										
	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other : Harmonic Imaging	Other : 3D
Ophthalmic											
Fetal		P	P	P	P	P	P		P*	P	P
Abdominal		P	P	P	P	P	P		P*	P	P
Intraoperative *Abdominal*											
Intraoperative Neurological											
Pediatric		P	P	P	P	P	P		P*	P	P
Small Organ (Specify) **		P	P	P	P	P	P		P*	P	P
Neonatal Cephalic											
Adult Cephalic											
Cardiac		N	N	N	N	N	N		N*	N	N
Trans-esophageal											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral vessel		N	N	N	N	N	N		N*	N	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:

*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+Color Doppler, B+CWD+Color Doppler, B+PWD+Color Doppler, B+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+M+Power Doppler

** 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)

David A Seyerm

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K032114

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: 5C2

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

Clinical Application	Mode of Operation										
	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other : Harmonic Imaging	Other : 3D
Ophthalmic											
Fetal		P	P	P	P	P	P		P*	P	P
Abdominal		P	P	P	P	P	P		P*	P	P
Intraoperative Abdominal											
Intraoperative Neurological											
Pediatric		P	P	P	P	P	P		P*	P	P
Small Organ (Specify) **											
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Trans-esophageal											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral vessel		N	N	N	N	N	N		N*	N	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:

*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+Color Doppler, B+CWD+Color Doppler, B+PWD+Color Doppler, B+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+M+Power Doppler

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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 K032114

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: 6C2

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

Clinical Application	Mode of Operation										
	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other : Harmonic Imaging	Other : 3D
Ophthalmic											
Fetal		P	P	P	P	P	P		P*	P	P
Abdominal		P	P	P	P	P	P		P*	P	P
Intraoperative Abdominal		P	P	P	P	P	P		P*	P	P
Intraoperative *Neurological*		P	P	P	P	P	P		P*	P	P
Pediatric		P	P	P	P	P	P		P*	P	P
Small Organ (Specify) **		P	P	P	P	P	P		P*	P	P
Neonatal Cephalic											
Adult Cephalic											
Cardiac		N	N	N	N	N	N		N*	N	N
Trans-esophageal											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral vessel		P	P	P	P	P	P		P*	P	P
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify) ***											

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

Additional Comments:

*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+Color Doppler, B+CWD+Color Doppler, B+PWD+Color Doppler, B+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+M+Power Doppler

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David R. Sigrom

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K032114

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: 8C4

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

Clinical Application	Mode of Operation										
	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other : Harmonic Imaging	Other : 3D
Ophthalmic											
Fetal		P	P	P	P	P	P		P*	P	P
Abdominal		P	P	P	P	P	P		P*	P	P
Intraoperative Abdominal		P	P	P	P	P	P		P*	P	P
Intraoperative Neurological		P	P	P	P	P	P		P*	P	P
Pediatric		P	P	P	P	P	P		P*	P	P
Small Organ (Specify) **											
Neonatal Cephalic											
Adult Cephalic											
Cardiac		N	N	N	N	N	N		N*	N	N
Trans-esophageal											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral vessel		N	N	N	N	N	N		N*	N	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:

*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+Color Doppler, B+CWD+Color Doppler, B+PWD+Color Doppler, B+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+M+Power Doppler

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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 K032114

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: EC10c5

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

Clinical Application	Mode of Operation										
	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other : Harmonic Imaging	Other : 3D
Ophthalmic											
Fetal											
Abdominal											
Intraoperative Abdominal											
Intraoperative Neurological											
Pediatric											
Small Organ (Specify) **											
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Trans-esophageal											
Transrectal		P	P	P		P	P		P*	P	P
Transvaginal		P	P	P		P	P		P*	P	P
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:

*Combinations include: B+M, B+PWD, B+Color Doppler, B+M+Color Doppler, B+PWD+Color Doppler, B+Power Doppler, B+PWD+Power Doppler, B+M+Power Doppler

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David R Hyman

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K032114

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **EV8C4**

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

Clinical Application	Mode of Operation										
	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other : Harmonic Imaging	Other : 3D
Ophthalmic											
Fetal		P	P	P	P	P	P		P*	P	P
Abdominal		P	P	P	P	P	P		P*	P	P
Intraoperative Abdominal											
Intraoperative Neurological											
Pediatric											
Small Organ (Specify) **											
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Trans-esophageal											
Transrectal											
Transvaginal		P	P	P	P	P	P		P*	P	P
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:

*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+Color Doppler, B+CWD+Color Doppler, B+PWD+Color Doppler, B+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+M+Power Doppler

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A. Lyman

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K032114

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: 6L3

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

Clinical Application	Mode of Operation										
	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other : Harmonic Imaging	Other : 3D
Ophthalmic											
Fetal		N	N	N	N	N	N		N*	N	N
Abdominal											
Intraoperative Abdominal		P	P	P	P	P	P		P*	P	P
Intraoperative Neurological		P	P	P	P	P	P		P*	P	P
Pediatric											
Small Organ (Specify) **		P	P	P	P	P	P		P*	P	P
Neonatal Cephalic											
Adult Cephalic											
Cardiac		N	N	N	N	N	N		N*	N	N
Trans-esophageal											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral vessel		P	P	P	P	P	P		P*	P	P
Laparoscopic											
Musculo-skeletal Conventional		P	P	P	P	P	P		P*	P	P
Musculo-skeletal Superficial		P	P	P	P	P	P		P*	P	P
Other (specify) ***											

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

Additional Comments:

*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+Color Doppler, B+CWD+Color Doppler, B+PWD+Color Doppler, B+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+M+Power Doppler

** 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, and Radiological Devices
510(k) Number K032114

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: Sequoia Diagnostic Ultrasound System, Harmonic Imaging

Transducer: AcuNav (IC10V5 or 10F10) diagnostic ultrasound catheter

Intended Use: For intra-cardiac and intra-luminal visualization of cardiac and great vessel anatomy and physiology, and visualization of other devices in the heart – use in right heart only.

Clinical Application	Mode of Operation										
	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other : Harmonic Imaging	Other : 3D
Ophthalmic											
Fetal											
Abdominal											
Intraoperative Abdominal											
Intraoperative Neurological											
Pediatric											
Small Organ (Specify) **											
Neonatal Cephalic											
Adult Cephalic											
Cardiac		P	P	P	P	P	P		P*		
Trans-esophageal											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral vessel											
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)***		P	P	P	P	P	P		P*		

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

Additional Comments:

*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+Color Doppler, B+CWD+Color Doppler, B+PWD+Color Doppler, B+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+M+Power Doppler

*** Other = Intra-luminal and Intra-cardiac

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A. Seymour

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K032114

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: 8L5

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

Clinical Application	Mode of Operation										
	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other : Harmonic Imaging	Other : 3D
Ophthalmic											
Fetal											
Abdominal											
Intraoperative Abdominal		P	P	P	P	P	P		P*	P	P
Intraoperative Neurological		P	P	P	P	P	P		P*	P	P
Pediatric											
Small Organ (Specify) **		P	P	P	P	P	P		P*	P	P
Neonatal Cephalic											
Adult Cephalic											
Cardiac		N	N	N	N	N	N		N*	N	N
Trans-esophageal											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral vessel		P	P	P	P	P	P		P*	P	P
Laparoscopic											
Musculo-skeletal Conventional		P	P	P	P	P	P		P*	P	P
Musculo-skeletal Superficial		P	P	P	P	P	P		P*	P	P
Other (specify) ***											

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

Additional Comments:

*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+Color Doppler, B+CWD+Color Doppler, B+PWD+Color Doppler, B+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+M+Power Doppler

** 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)

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K032114

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **8L5T**

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

Clinical Application	Mode of Operation										
	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other : Harmonic Imaging	Other : 3D
Ophthalmic											
Fetal											
Abdominal											
Intraoperative Abdominal		P	P	P	P	P	P		P*	P	P
Intraoperative Neurological		P	P	P	P	P	P		P*	P	P
Pediatric		P	P	P	P	P	P		P*	P	P
Small Organ (Specify) **		P	P	P	P	P	P		P*	P	P
Neonatal Cephalic											
Adult Cephalic											
Cardiac		P	P	P	P	P	P		P*	P	P
Trans-esophageal											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral vessel		P	P	P	P	P	P		P*	P	P
Laparoscopic											
Musculo-skeletal Conventional		P	P	P	P	P	P		P*	P	P
Musculo-skeletal Superficial		P	P	P	P	P	P		P*	P	P
Other (specify) ***											

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

Additional Comments:

*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+Color Doppler, B+CWD+Color Doppler, B+PWD+Color Doppler, B+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+M+Power Doppler

** 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)

David R. Hyman

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K032114

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **13L5SP**

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

Clinical Application	Mode of Operation										
	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other : Harmonic Imaging	Other : 3D
Ophthalmic											
Fetal											
Abdominal											
Intraoperative Abdominal		P	P	P	P	P	P		P*	P	P
Intraoperative Neurological		P	P	P	P	P	P		P*	P	P
Pediatric		P	P	P	P	P	P		P*	P	P
Small Organ (Specify) **		P	P	P	P	P	P		P*	P	P
Neonatal Cephalic											
Adult Cephalic											
Cardiac		P	P	P	P	P	P		P*	P	P
Trans-esophageal											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral vessel		P	P	P	P	P	P		P*	P	P
Laparoscopic											
Musculo-skeletal Conventional		P	P	P	P	P	P		P*	P	P
Musculo-skeletal Superficial		P	P	P	P	P	P		P*	P	P
Other (specify) ***											

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

Additional Comments:

*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+Color Doppler, B+CWD+Color Doppler, B+PWD+Color Doppler, B+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+M+Power Doppler

** 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, and Radiological Devices
510(k) Number K032114

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **15L8**

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

Clinical Application	Mode of Operation										
	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other : Harmonic Imaging	Other : 3D
Ophthalmic											
Fetal											
Abdominal											
Intraoperative Abdominal		P	P	P	P	P	P		P*	P	P
Intraoperative Neurological		P	P	P	P	P	P		P*	P	P
Pediatric		N	N	N	N	N	N		N*	N	N
Small Organ (Specify) **		P	P	P	P	P	P		P*	P	P
Neonatal Cephalic											
Adult Cephalic											
Cardiac		P	P	P		P	P		P*	P	P
Trans-esophageal											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral vessel		P	P	P	P	P	P		P*	P	P
Laparoscopic											
Musculo-skeletal Conventional		P	P	P	P	P	P		P*	P	P
Musculo-skeletal Superficial		P	P	P	P	P	P		P*	P	P
Other (specify) ***											

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

Additional Comments:

*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+Color Doppler, B+CWD+Color Doppler, B+PWD+Color Doppler, B+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+M+Power Doppler

** 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)

David B. Eggum

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K032114

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: 15L8w

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

Clinical Application	Mode of Operation										
	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other : Harmonic Imaging	Other : 3D
Ophthalmic											
Fetal		P	P	P		P	P		P*		P
Abdominal		P	P	P		P	P		P*		P
Intraoperative Abdominal		P	P	P		P	P		P*		P
Intraoperative Neurological		P	P	P		P	P		P*		P
Pediatric		P	P	P		P	P		P*		P
Small Organ (Specify) **		P	P	P		P	P		P*		P
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Trans-esophageal											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral vessel		P	P	P		P	P		P*		P
Laparoscopic											
Musculo-skeletal Conventional		P	P	P		P	P		P*		P
Musculo-skeletal Superficial		P	P	P		P	P		P*		P
Other (specify) ***											

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

Additional Comments:

*Combinations include: B+M, B+PWD, B+Color Doppler, B+M+Color Doppler, B+PWD+Color Doppler, B+Power Doppler, B+PWD+Power Doppler, B+M+Power Doppler

** 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)

David A. Lyon

sion Sign-Off)
ion of Reproductive, Abdominal,
adiological Devices
) Number K032114

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **V5M TEE**

Intended Use: *Ultrasound imaging or fluid flow analysis of the human body as follows:*

Clinical Application	Mode of Operation										
	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other : Harmonic Imaging	Other : 3D
Ophthalmic											
Fetal											
Abdominal		P	P	P	P	P	P		P*	P	P
Intraoperative Abdominal											
Intraoperative Neurological											
Pediatric		P	P	P	P	P	P			P	P
Small Organ (Specify) **											
Neonatal Cephalic											
Adult Cephalic											
Cardiac		P	P	P	P	P	P		P*	P	P
Trans-esophageal		P	P	P	P	P	P		P*	P	P
Transrectal											
Transvaginal											
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:

*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+Color Doppler, B+CWD+Color Doppler, B+PWD+Color Doppler, B+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+M+Power Doppler

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K032114

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **V7M TEE**

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

Clinical Application	Mode of Operation										
	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other : Harmonic Imaging	Other : 3D
Ophthalmic											
Fetal											
Abdominal		P	P	P	P	P	P		P*	P	P
Intraoperative Abdominal											
Intraoperative Neurological											
Pediatric		P	P	P	P	P	P		P*	P	P
Small Organ (Specify) **											
Neonatal Cephalic											
Adult Cephalic											
Cardiac		P	P	P	P	P	P		P*	P	P
Trans-esophageal		P	P	P	P	P	P		P*	P	P
Transrectal											
Transvaginal											
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:

*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+Color Doppler, B+CWD+Color Doppler, B+PWD+Color Doppler, B+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+M+Power Doppler

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A. Lehyman

(Division Sign-Off)
Division of **Reproductive, Abdominal,** and Radiological Devices
510(k) Number K032114

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **V7B TEE**

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

Clinical Application	Mode of Operation										
	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other : Harmonic Imaging	Other : 3D
Ophthalmic											
Fetal											
Abdominal		P	P	P	P	P	P		P*	P	P
Intraoperative Abdominal											
Intraoperative Neurological											
Pediatric		P	P	P	P	P	P		P*	P	P
Small Organ (Specify) **											
Neonatal Cephalic											
Adult Cephalic											
Cardiac		P	P	P	P	P	P		P*	P	P
Trans-esophageal		P	P	P	P	P	P		P*	P	P
Transrectal											
Transvaginal											
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:

*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+Color Doppler, B+CWD+Color Doppler, B+PWD+Color Doppler, B+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+M+Power Doppler

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David G. Lytton

(Division **Sign-Off**)
Division of **Reproductive, Abdominal,**
and **Radiological Devices**
510(k) Number K021147

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **3V2c**

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

Clinical Application	Mode of Operation										
	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other : Harmonic Imaging	Other : 3D
Ophthalmic											
Fetal		P	P	P	P	P	P		P*	P	P
Abdominal		P	P	P	P	P	P		P*	P	P
Intraoperative Abdominal											
Intraoperative Neurological											
Pediatric		P	P	P	P	P	P		P*	P	P
Small Organ (Specify) **											
Neonatal Cephalic											
Adult Cephalic		P	P	P	P	P	P		P*	P	P
Cardiac		P	P	P	P	P	P		P*	P	P
Trans-esophageal											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral vessel											
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify) ***		P	P	P	P	P	P		P*	P	P

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

Additional Comments:

*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+Color Doppler, B+CWD+Color Doppler, B+PWD+Color Doppler, B+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+M+Power Doppler

*** neonatal cardiac

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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 K032114

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: 4V1

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

Clinical Application	Mode of Operation										
	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other : Harmonic Imaging	Other : 3D
Ophthalmic											
Fetal		P	P	P		P	P		P*	P	P
Abdominal		P	P	P		P	P		P*	P	P
Intraoperative Abdominal		P	P	P		P	P		P*	P	P
Intraoperative Neurological											
Pediatric		P	P	P		P	P		P*	P	P
Small Organ (Specify) **											
Neonatal Cephalic											
Adult Cephalic											
Cardiac		N	N	N		N	N		N*	N	N
Trans-esophageal											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral vessel		N	N	N		N	N		N*	N	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:

*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+Color Doppler, B+CWD+Color Doppler, B+PWD+Color Doppler, B+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+M+Power Doppler

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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 K032114

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **4V1c (Sirius)**

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

Clinical Application	Mode of Operation										
	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other : Harmonic Imaging	Other : 3D
Ophthalmic											
Fetal		P	P	P	P	P	P		P*	P	P
Abdominal		P	P	P	P	P	P		P*	P	P
Intraoperative Abdominal		P	P	P	P	P	P		P*	P	P
Intraoperative Neurological		P	P	P	P	P	P		P*	P	P
Pediatric		P	P	P	P	P	P		P*	P	P
Small Organ (Specify) **											
Neonatal Cephalic											
Adult Cephalic		P	P	P	P	P	P		P*	P	P
Cardiac		P	P	P	P	P	P		P*	P	P
Trans-esophageal											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral vessel		P	P	P	P	P	P		P*	P	P
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify) ***		P	P	P	P	P	P		P*	P	P

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

Additional Comments:

*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+Color Doppler, B+CWD+Color Doppler, B+PWD+Color Doppler, B+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+M+Power Doppler

*** neonatal cardiac

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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,**
[illegible]ological Devices
[illegible] Number K032114

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **4V2**

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

Clinical Application	Mode of Operation										
	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other : Harmonic Imaging	Other : 3D
Ophthalmic											
Fetal		P	P	P	P	P	P		P*	P	P
Abdominal		P	P	P	P	P	P		P*	P	P
Intraoperative Abdominal											
Intraoperative Neurological											
Pediatric		P	P	P	P	P	P		P*	P	P
Small Organ (Specify) **											
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Trans-esophageal											
Transrectal											
Transvaginal											
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:

*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+PWD+Color Doppler, B+Power Doppler, B+PWD+Power Doppler

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David R Sperm

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K032114

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **5V2c**

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

Clinical Application	Mode of Operation										
	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other : Harmonic Imaging	Other : 3D
Ophthalmic											
Fetal		P	P	P	P	P	P		P*	P	P
Abdominal		P	P	P	P	P	P		P*	P	P
Intraoperative Abdominal											
Intraoperative Neurological											
Pediatric		P	P	P	P	P	P		P*	P	P
Small Organ (Specify) **											
Neonatal Cephalic											
Adult Cephalic											
Cardiac		P	P	P	P	P	P		P*	P	P
Trans-esophageal											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral vessel		N	N	N	N	N	N		N*	N	N
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify) ***		P	P	P	P	P	P		P*	P	P

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

Additional Comments:

*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+Color Doppler, B+CWD+Color Doppler, B+PWD+Color Doppler, B+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+M+Power Doppler

*** neonatal cardiac

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David R. Lyerman

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K032114

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **7V3c**

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

Clinical Application	Mode of Operation										
	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other : Harmonic Imaging	Other : 3D
Ophthalmic											
Fetal		P	P	P	P	P	P		P*	P	P
Abdominal		P	P	P	P	P	P		P*	P	P
Intraoperative Abdominal		P	P	P	P	P	P		P*	P	P
Intraoperative Neurological		P	P	P	P	P	P		P*	P	P
Pediatric		P	P	P	P	P	P		P*	P	P
Small Organ (Specify) **											
Neonatal Cephalic		P	P	P	P	P	P		P*	P	P
Adult Cephalic											
Cardiac		P	P	P	P	P	P		P*	P	P
Trans-esophageal											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral vessel		N	N	N	N	N	N		N*	N	N
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify) ***		P	P	P	P	P	P		P*	P	P

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

Additional Comments:

*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+Color Doppler, B+CWD+Color Doppler, B+PWD+Color Doppler, B+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+M+Power Doppler

*** neonatal cardiac

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A Seymour

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K032114

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **Gemini**

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

Clinical Application	Mode of Operation										
	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other : Harmonic Imaging	Other : 3D
Ophthalmic											
Fetal		N	N	N	N	N	N		N*	N	
Abdominal		N	N	N	N	N	N		N*	N	
Intraoperative Abdominal		N	N	N	N	N	N		N*	N	
Intraoperative Neurological		N	N	N	N	N	N		N*	N	
Pediatric		N	N	N	N	N	N		N*	N	
Small Organ (Specify) **											
Neonatal Cephalic		N	N	N	N	N	N		N*	N	
Adult Cephalic											
Cardiac		N	N	N	N	N	N		N*	N	
Trans-esophageal											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral vessel											
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify) ***		N	N	N	N	N	N		N*	N	

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

Additional Comments:

*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+Color Doppler, B+CWD+Color Doppler, B+PWD+Color Doppler, B+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+M+Power Doppler

*** neonatal cardiac

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A. Legorm

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K032114

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **8V5**

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

Clinical Application	Mode of Operation										
	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other : Harmonic Imaging	Other : 3D
Ophthalmic											
Fetal		P	P	P	P	P	P		P*	P	P
Abdominal		P	P	P	P	P	P		P*	P	P
Intraoperative Abdominal		P	P	P	P	P	P		P*	P	P
Intraoperative Neurological		P	P	P	P	P	P		P*	P	P
Pediatric		P	P	P	P	P	P		P*	P	P
Small Organ (Specify) **											
Neonatal Cephalic		P	P	P	P	P	P		P*	P	P
Adult Cephalic											
Cardiac		P	P	P	P	P	P		P*	P	P
Trans-esophageal											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral vessel		N	N	N	N	N	N		N*	N	N
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify) ***		P	P	P	P	P	P		P*	P	P

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

Additional Comments:

*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+Color Doppler, B+CWD+Color Doppler, B+PWD+Color Doppler, B+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+M+Power Doppler

*** neonatal cardiac

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A. Eigman

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K032114

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: 10V4

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

Clinical Application	Mode of Operation										
	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other : Harmonic Imaging	Other : 3D
Ophthalmic											
Fetal		P	P	P	P	P	P		P*	P	P
Abdominal		P	P	P	P	P	P		P*	P	P
Intraoperative Abdominal		P	P	P	P	P	P		P*	P	P
Intraoperative Neurological		P	P	P	P	P	P		P*	P	P
Pediatric		P	P	P	P	P	P		P*	P	P
Small Organ (Specify) **		P	P	P	P	P	P		P*	P	P
Neonatal Cephalic		P	P	P	P	P	P		P*	P	P
Adult Cephalic											
Cardiac		P	P	P	P	P	P		P*	P	P
Trans-esophageal											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral vessel											
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify) ***		P	P	P	P	P	P		P*	P	P

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

Additional Comments:

*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+Color Doppler, B+CWD+Color Doppler, B+PWD+Color Doppler, B+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+M+Power Doppler

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

*** neonatal cardiac

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A. Seymour

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K032114

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **AUX CW**

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

Clinical Application	Mode of Operation										
	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other : Harmonic Imaging	Other : 3D
Ophthalmic											
Fetal											
Abdominal											
Intraoperative Abdominal											
Intraoperative Neurological											
Pediatric					P						
Small Organ (Specify) **											
Neonatal Cephalic											
Adult Cephalic											
Cardiac					P						
Trans-esophageal											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral vessel					P						
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)

David A. Seguson

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Division of Reproductive, Abdominal,
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510(k) Number K032114