JUN - 7 2004

SECTION 11

510(k) Summary of Safety and Effectiveness

Siemens Medical Solutions USA, Inc., Ultrasound Division has not disclosed its intent to market this device modification and requests this notification be held CONFIDENTIAL by the FDA, and not be released to any Freedom of Information request or addressed with any outside parties.

Sponsor: Siemens Medical Solutions USA, Inc., Ultrasound Division
1230 Shorebird Way
P.O. Box 7393
Mountain View, California 94039-7393

Contact Person: Iskra Mraković
Manager of Regulatory Affairs
Telephone: (650) 694-5004
Fax: (650) 943-7053

Submission Date: May 13, 2004

Device Name: Sequoia Diagnostic Ultrasound System

Common Name: Diagnostic Ultrasound System with Accessories

Classification:

Regulatory Class: II
Review Category: Tier II
Classification Panel: Radiology

21 CFR 892.1550

	FR #	Product Code
Ultrasonic Pulsed Doppler Imaging System	892.1550	90-IYN
Ultrasonic Pulsed Echo Imaging System	892.1560	90-IYO
Diagnostic Ultrasound Transducer	892.1570	90-ITX
Diagnostic Intravascular Catheter	870.1200	90-DQO

Predicate Devices:

- # K032114 (July 21, 2003) cleared as ACUSON® Sequoia 8.0 Diagnostic Ultrasound System.
- # K033196 (October 16, 2003) cleared as SONOLINE® Antares Diagnostic Ultrasound System with Clarify™ VE.

Device Description:

The Sequoia system is a multi-purpose diagnostic ultrasound system with accessories and proprietary software, and is substantially equivalent to our current product that is already cleared for USA distribution under the following 510(k) PreMarket Notification number:

- # K032114 (July 21, 2003) cleared as ACUSON® Sequoia 8.0 Diagnostic Ultrasound System.

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 Device Directive
- Safety and EMC Requirements for Medical Equipment
- EN 60601-1
  - EN 60601-1-1
  - EN 60601-1-2
- ISO 10993 Biocompatibility
- The system's acoustic output is in accordance with ALARA principle (as low as reasonably achievable)

Intended Use:

The Sequoia platform is intended for use in the following applications:

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-sceletal (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 for analysis packages that provide information that is used for clinical diagnosis purposes.

Technological Comparison to Predicate Device:

The Sequoia is substantially equivalent in its technologies and functionality to the Sequoia 8.0 Diagnostic Ultrasound System that is already cleared under 510(k) premarket notification number K032114.

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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 7 2004

Mr. Iskra Mraković
Manager, Regulatory Affairs
Siemens Medical Solutions USA, Inc.
Ultrasound Division
1230 Shorebird Way
P.O. Box 7393
MOUNTAIN VIEW CA 94039-7393

Re: K041319
Trade Name: Sequoia 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: May 17, 2004
Received: May 18, 2004

Dear Mr. Mraković:

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 Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

4C1	EC10c5	8L5T
5C2	EV8C4	13L5SP
6C2	6L3	15L8
8C4	8L5	15L8w

V5M TEE	4V1c	8V5
V7M TEE	4V2	10V4
V7B TEE	5V2c	AUX CW
3V2c	7V3c	AcuNav (IC10V5 or 10F10)
4V1	8V3	

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 (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,

Nancy C. Brogdon

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 Diagnostic Ultrasound System**

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

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

P=previously cleared by the FDA under premarket notifications #K033650 and #K033196.

Additional Comments:

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

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

***neonatal cardiac

(PLESE 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)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K041319

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	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging
Ophthalmic										
Fetal		P	P	P	P	P	P		P*	P
Abdominal		P	P	P	P	P	P		P*	P
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric		P	P	P	P	P	P		P*	P
Small Organ (specify)**		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
Laparoscopic										
Musculo-skeletal (Conventional)										
Musculo-skeletal (Superficial)										
Other (specify)										

P=previously cleared by the FDA under premarket notifications #K033650 and #K033196.

Additional Comments:

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

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

(PLESE 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)

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K041319

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	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging
Ophthalmic										
Fetal		P	P	P	P	P	P		P*	P
Abdominal		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
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vessel		P	P	P	P	P	P		P*	P
Laparoscopic										
Musculo-skeletal (Conventional)										
Musculo-skeletal (Superficial)										
Other (specify)										

P=previously cleared by the FDA under premarket notifications #K033650 and #K033196.

Additional Comments:

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

(PLESE 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)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K041316

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	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging
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		P	P	P	P	P	P		P*	P
Pediatric		P	P	P	P	P	P		P*	P
Small Organ (specify)**		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
Laparoscopic										
Musculo-skeletal (Conventional)										
Musculo-skeletal (Superficial)										
Other (specify)										

P=previously cleared by the FDA under premarket notifications #K033650 and #K033196.

Additional Comments:

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

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

(PLESE 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)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K043194

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	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging
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		P	P	P	P	P	P		P*	P
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
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vessel		P	P	P	P	P	P		P*	P
Laparoscopic										
Musculo-skeletal (Conventional)										
Musculo-skeletal (Superficial)										
Other (specify)										

P=previously cleared by the FDA under premarket notifications #K033650 and #K033196.

Additional Comments:

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

(PLESE 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)

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K041319

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	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging
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)										

P=previously cleared by the FDA under premarket notifications #K033650 and #K033196.

Additional Comments:

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

(PLESE 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)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K041319

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	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging
Ophthalmic										
Fetal		P	P	P	P	P	P		P*	P
Abdominal		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
Transurethral										
Intravascular										
Peripheral Vessel										
Laparoscopic										
Musculo-skeletal (Conventional)										
Musculo-skeletal (Superficial)										
Other (specify)										

P=previously cleared by the FDA under premarket notifications #K033650 and #K033196.

Additional Comments:

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

(PLESE 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)

Nancy C Brogdon
(Division Sign-Off)
Division of **Reproductive, Abdominal,**
and **Radiological Devices**
510(k) Number K041319

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	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging
Ophthalmic										
Fetal		P	P	P	P	P	P		P*	P
Abdominal										
Intraoperative Abdominal		P	P	P	P	P	P		P*	P
Intraoperative Neurological		P	P	P	P	P	P		P*	P
Pediatric										
Small Organ (specify)**		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
Laparoscopic										
Musculo-skeletal (Conventional)		P	P	P	P	P	P		P*	P
Musculo-skeletal (Superficial)		P	P	P	P	P	P		P*	P
Other (specify)										

P=previously cleared by the FDA under premarket notifications #K033650 and #K033196.

Additional Comments:

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

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

(PLESE 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)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K041319

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	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging
Ophthalmic										
Fetal										
Abdominal										
Intraoperative Abdominal		P	P	P	P	P	P		P*	P
Intraoperative Neurological		P	P	P	P	P	P		P*	P
Pediatric										
Small Organ (specify)**		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
Laparoscopic										
Musculo-skeletal (Conventional)		P	P	P	P	P	P		P*	P
Musculo-skeletal (Superficial)		P	P	P	P	P	P		P*	P
Other (specify)										

P=previously cleared by the FDA under premarket notifications #K033650 and #K033196.

Additional Comments:

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

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

(PLESE 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)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K041319

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	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging
Ophthalmic										
Fetal										
Abdominal										
Intraoperative Abdominal		P	P	P	P	P	P		P*	P
Intraoperative Neurological		P	P	P	P	P	P		P*	P
Pediatric		P	P	P	P	P	P		P*	P
Small Organ (specify)**		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
Laparoscopic										
Musculo-skeletal (Conventional)		P	P	P	P	P	P		P*	P
Musculo-skeletal (Superficial)		P	P	P	P	P	P		P*	P
Other (specify)										

P=previously cleared by the FDA under premarket notifications #K033650 and #K033196.

Additional Comments:

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

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

(PLESE 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)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K041319

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	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging
Ophthalmic										
Fetal										
Abdominal										
Intraoperative Abdominal		P	P	P	P	P	P		P*	P
Intraoperative Neurological		P	P	P	P	P	P		P*	P
Pediatric		P	P	P	P	P	P		P*	P
Small Organ (specify)**		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
Laparoscopic										
Musculo-skeletal (Conventional)		P	P	P	P	P	P		P*	P
Musculo-skeletal (Superficial)		P	P	P	P	P	P		P*	P
Other (specify)										

P=previously cleared by the FDA under premarket notifications #K033650 and #K033196.

Additional Comments:

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

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

(PLESE 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)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K041319

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	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging
Ophthalmic										
Fetal										
Abdominal										
Intraoperative Abdominal		P	P	P	P	P	P		P*	P
Intraoperative Neurological		P	P	P	P	P	P		P*	P
Pediatric		P	P	P	P	P	P		P*	P
Small Organ (specify)**		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
Laparoscopic										
Musculo-skeletal (Conventional)		P	P	P	P	P	P		P*	P
Musculo-skeletal (Superficial)		P	P	P	P	P	P		P*	P
Other (specify)										

P=previously cleared by the FDA under premarket notifications #K033650 and #K033196.

Additional Comments:

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

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

(PLESE 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)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K041319

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	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging
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		P	P	P	P	P	P		P*	P
Pediatric		P	P	P	P	P	P		P*	P
Small Organ (specify)**		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
Laparoscopic										
Musculo-skeletal (Conventional)		P	P	P	P	P	P		P*	P
Musculo-skeletal (Superficial)		P	P	P	P	P	P		P*	P
Other (specify)										

P=previously cleared by the FDA under premarket notifications #K033650 and #K033196.

Additional Comments:

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

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

(PLESE 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)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K041319

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	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging
Ophthalmic										
Fetal										
Abdominal		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
Trans-esophageal		P	P	P	P	P	P		P*	P
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vessel										
Laparoscopic										
Musculo-skeletal (Conventional)										
Musculo-skeletal (Superficial)										
Other (specify)										

P=previously cleared by the FDA under premarket notifications #K033650 and #K033196.

Additional Comments:

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

(PLESE 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)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K041319

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	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging
Ophthalmic										
Fetal										
Abdominal		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
Trans-esophageal		P	P	P	P	P	P		P*	P
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vessel										
Laparoscopic										
Musculo-skeletal (Conventional)										
Musculo-skeletal (Superficial)										
Other (specify)										

P=previously cleared by the FDA under premarket notifications #K033650 and #K033196.

Additional Comments:

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

(PLESE 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)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K041319

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	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging
Ophthalmic										
Fetal										
Abdominal		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
Trans-esophageal		P	P	P	P	P	P		P*	P
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vessel										
Laparoscopic										
Musculo-skeletal (Conventional)										
Musculo-skeletal (Superficial)										
Other (specify)										

P=previously cleared by the FDA under premarket notifications #K033650 and #K033196.

Additional Comments:

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

(PLESE 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)

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K041319

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

P=previously cleared by the FDA under premarket notifications #K033650 and #K033196.

Additional Comments:

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

***neonatal cardiac

(PLESE 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)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K041319

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	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging
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		P	P	P	P	P	P		P*	P
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vessel		P	P	P	P	P	P		P*	P
Laparoscopic										
Musculo-skeletal (Conventional)										
Musculo-skeletal (Superficial)										
Other (specify)										

P=previously cleared by the FDA under premarket notifications #K033650 and #K033196.

Additional Comments:

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

(PLESE 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)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K041319

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **4V1c**

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

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging
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		P	P	P	P	P	P		P*	P
Pediatric		P	P	P	P	P	P		P*	P
Small Organ (specify)**										
Neonatal Cephalic										
Adult Cephalic		P	P	P	P	P	P		P*	P
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
Laparoscopic										
Musculo-skeletal (Conventional)										
Musculo-skeletal (Superficial)										
Other (specify)***		P	P	P	P	P	P		P*	P

P=previously cleared by the FDA under premarket notifications #K033650 and #K033196.

Additional Comments:

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

***neonatal cardiac

(PLESE 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)

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K044319

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	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging
Ophthalmic										
Fetal		P	P	P	P	P	P		P*	P
Abdominal		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										
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vessel										
Laparoscopic										
Musculo-skeletal (Conventional)										
Musculo-skeletal (Superficial)										
Other (specify)										

P=previously cleared by the FDA under premarket notifications #K033650 and #K033196.

Additional Comments:

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

(PLESE 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)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K041319

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	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging
Ophthalmic										
Fetal		P	P	P	P	P	P		P*	P
Abdominal		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
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vessel		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=previously cleared by the FDA under premarket notifications #K033650 and #K033196.

Additional Comments:

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

***neonatal cardiac

(PLESE 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)

Nancy C. Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K041319

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	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging
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		P	P	P	P	P	P		P*	P
Pediatric		P	P	P	P	P	P		P*	P
Small Organ (specify)**										
Neonatal Cephalic		P	P	P	P	P	P		P*	P
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
Laparoscopic										
Musculo-skeletal (Conventional)										
Musculo-skeletal (Superficial)										
Other (specify)***		P	P	P	P	P	P		P*	P

P=previously cleared by the FDA under premarket notifications #K033650 and #K033196.

Additional Comments:

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

***neonatal cardiac

(PLESE 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)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K041319

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **8V3**

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

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging
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		P	P	P	P	P	P		P*	P
Pediatric		P	P	P	P	P	P		P*	P
Small Organ (specify)**										
Neonatal Cephalic		P	P	P	P	P	P		P*	P
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
Laparoscopic										
Musculo-skeletal (Conventional)										
Musculo-skeletal (Superficial)										
Other (specify)***		P	P	P	P	P	P		P*	P

P=previously cleared by the FDA under premarket notifications #K033650 and #K033196.

Additional Comments:

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

***neonatal cardiac

(PLESE 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)

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K041319

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	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging
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		P	P	P	P	P	P		P*	P
Pediatric		P	P	P	P	P	P		P*	P
Small Organ (specify)**										
Neonatal Cephalic		P	P	P	P	P	P		P*	P
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
Laparoscopic										
Musculo-skeletal (Conventional)										
Musculo-skeletal (Superficial)										
Other (specify)***		P	P	P	P	P	P		P*	P

P=previously cleared by the FDA under premarket notifications #K033650 and #K033196.

Additional Comments:

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

***neonatal cardiac

(PLESE 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)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K043179

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	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging
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		P	P	P	P	P	P		P*	P
Pediatric		P	P	P	P	P	P		P*	P
Small Organ (specify)**		P	P	P	P	P	P		P*	P
Neonatal Cephalic		P	P	P	P	P	P		P*	P
Adult Cephalic										
Cardiac		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=previously cleared by the FDA under premarket notifications #K033650 and #K033196.

Additional Comments:

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

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

***neonatal cardiac

(PLESE 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)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K041319

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	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging
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)										

P=previously cleared by the FDA under premarket notification # K032114.

Additional Comments:

(PLESE 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)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K041319

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: Sequoia Diagnostic Ultrasound System, Harmonic Imaging

Transducer: **AcuNav (1C10V5 or 10F10) Diagnostic Ultrasound Catheter**

Indications for Use: The AcuNav™ Diagnostic Ultrasound Catheter is intended fur intra-cardiac and intra-luminal visualization of cardiac and great vessel anatomy and physiology as well as visualization of other devices in the heart.

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

P=previously cleared by the FDA under premarket notifications #K033650 and #K033196.

Additional Comments:

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

(PLESE 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

Nancy C Brogdon

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

510(k) Number K041319