

**SUMMARY OF SAFETY AND EFFECTIVENESS**

DEC 23 1997

**I. GENERAL INFORMATION**

Device generic name: Ultrasonic Pulsed Doppler Imaging System,  
Ultrasonic Pulsed Echo Imaging System, and  
Diagnostic Ultrasound Transducer

Device Trade Name: Sequoia™ Ultrasound System and Harmonic Imaging  
with Contrast Option

510(k) No: \_\_\_\_\_

Date of 510(k) submission September 25, 1997

**II. INDICATION FOR USE:**

The Sequoia™ Ultrasound System in conjunction with the administration of ultrasound contrast agents applies ultrasound energy to an organ, vessel/structure to improve opacification, increase delineation, enhance color Doppler and/or spectral Doppler response, increase visualization of blood flow, document uptake of contrast agent and/or demonstrate perfusion of tissue. The images obtained are useful to physicians in detecting normal and abnormal conditions in regions of the body.

**III. DEVICE DESCRIPTION**

The Sequoia™ Ultrasound System with the Harmonic Imaging with Contrast utilizes the previously cleared Sequoia™ Ultrasound system (Acuson Model 3001- K935595/S1) and its transcutaneous as well as invasive transducers to create 2-D, M-mode, color Doppler and Spectral Doppler displays of acoustic data in conjunction with administration of ultrasound contrast agent. There are two primary methods by which images are created. First, the images are created in primary imaging mode, with exactly the same transmit and receive settings and controls as are utilized for routine ultrasound imaging without contrast agent administration. Second, images are created in harmonic imaging mode, with the images created using the same transmit settings and controls as are utilized for routine ultrasound imaging without contrast agent administration but in addition the receive frequency is a multiple of the transmit frequency. In both primary and harmonic imaging, exams can be performed using the standard frame rates applicable during routine ultrasound exams. the number of cycles utilized in routine exams.

#### **IV. WARNING AND PRECAUTIONS**

The addition of Harmonic Imaging with Contrast option did not result in the addition of new warning or precautions related to the ultrasound system. Labeling was changed to reflect warnings usually associated with the administration of contrast agents and to provide user information related to operation of the system in conjunction with the administration of contrast agents.

#### **V. POTENTIAL ADVERSE EFFECTS**

Addition of Harmonic Imaging with Contrast did not introduce any new potential hazards to the use of the Sequoia Ultrasound System and transducers. Since the introduction of the Sequoia system to the ultrasound market, no adverse health effects to the patient and user population have been confirmed.

#### **VI. BIOCOMPATIBILITY**

No material changes to the Sequoia transducers were necessary to add Harmonic Imaging with Contrast. Biocompatibility data for all Acuson transducer materials contacting patients is on file.

#### **VII. IMAGING PERFORMANCE**

Clinical studies were conducted to verify the performance of the system in all imaging modes. Clinical data was submitted as part of the Harmonic Imaging with Contrast 510(k).



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

DEC 23 1997

William Welch  
Regulatory Affairs Manager  
Acuson Corporation  
1220 Charleston Road  
P.O. Box 7393  
Mountain View, CA 94039-7393

Re: K973767  
Harmonic Imaging with Contrast Option  
(for the Sequoia™ Ultrasound System)  
Dated: July 25, 1997  
Received: October 2, 1997  
Regulatory class: II  
21 CFR 892.1550/Procode: 90 IYN  
21 CFR 892.1560/Procode: 90 IYO  
21 CFR 892.1570/Procode: 90 ITX

Dear Mr. Welch:

We have reviewed your section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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. You may, therefore, market the device, subject to the general controls provisions Act (Act). The general controls provisions of the Act include requirements for registration, listing of devices, good manufacturing practices, labeling, and prohibitions against misbranding and adulteration.

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

Transducer Model Number

TE-V5M  
8L5  
6L3  
15L8  
8V5  
7V3c  
5V2c  
3V2c  
8C4  
5C2  
4V2  
EV-8C4  
Aux CW

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General (GMP) regulation (21 CFR Part

820) and that, through periodic QS inspections, the FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register.

*Please note:* this response to your premarket notification does not affect any obligation you may have under sections 531 and 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report.

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

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

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

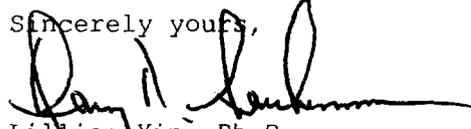
This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

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

Page 3 - William Welch

If you have any questions regarding the content of this letter, please contact Paul Gammell, Ph.D. at (301) 594-1212.

Sincerely yours,



for

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

Enclosure



**Diagnostic Ultrasound Indications for Use Form**

**Fill out one form for each ultrasound system and transducer**

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

The TE-V5M transducer is intended for Harmonic Imaging and Conventional Contrast Imaging in conjunction with legally marketed contrast agents for the indications that they have been approved".

Ultrasound System: Sequoia™

Transducer: TE-V5M

Clinical Applications	A	B	M	PWD	CWD	Color Doppler	Power (Ampl.) Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify) Harmonic Imaging
Ophthalmic										
Fetal										
Abdominal (P)		x	x	x	x	x	x		*	x
Intra-operative - abdominal - cardiac										
Intra-operative Neurological										
Pediatric										
Small Organ - Thyroid - Breast - Testicle										
Neonatal Cephalic										
Adult Cephalic										
Cardiac		x	x	x	x	x	x		*	x
Trans-esophageal		x	x	x	x	x	x		*	x
Trans-Rectal										
Trans-Vaginal										
Trans-Urethral										
Intra-Luminal										
Peripheral Vascular										
Laparoscopic										
Musculo-Skeletal Conventional										
Musculo-Skeletal Superficial										
Other (Specify)										

**Additional Comments:**

\* Combinations: 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

(Division Sign-Off)  
 Division of Reproductive, Abdominal, ENT,  
 and Radiological Devices  
 510(k) Number K973767

Prescription Use   
 (Per 21 CFR 801.109)

**Diagnostic Ultrasound Indications for Use Form**

**Fill out one form for each ultrasound system and transducer**

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

The 8L5 transducer is intended for Harmonic Imaging and Conventional Contrast Imaging in conjunction with legally marketed contrast agents for the indications that they have been approved".

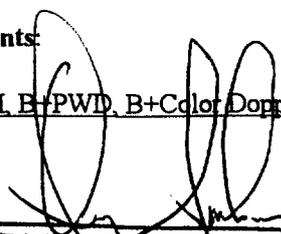
Ultrasound System: Sequoia™

Transducer: 8L5

Clinical Applications	A	B	M	PWD	CWD	Color Doppler	Power (Ampl.) Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify) Harmonic Imaging
Ophthalmic										
Fetal										
Abdominal										
Intra-operative - vascular		x	x	x	x	x	x		*	x
Intra-operative Neurological										
Pediatric										
Small Organ - Thyroid - Breast - Testicle		x	x	x	x	x	x		*	x
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal										
Trans-Rectal										
Trans-Vaginal										
Trans-Urethral										
Intra-Luminal										
Peripheral Vascular		x	x	x	x	x	x		*	
Laparoscopic										x
Musculo-Skeletal Conventional		x	x	x	x	x	x		*	x
Musculo-Skeletal Superficial		x	x	x	x	x	x		*	x
Other (Specify)										

Additional Comments:

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

  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal, ENT,  
 and Radiological Devices  
 510(k) Number K973767

Prescription Use   
 (Per 21 CFR 801.109)

## Diagnostic Ultrasound Indications for Use Form

**Fill out one form for each ultrasound system and transducer**

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

The 6L3 transducer is intended for Harmonic Imaging and Conventional Contrast Imaging in conjunction with legally marketed contrast agents for the indications that they have been approved".

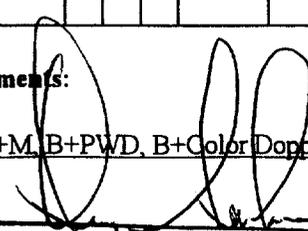
Ultrasound System: Sequoia™

Transducer: 6L3

Clinical Applications	A	B	M	PWD	CWD	Color Doppler	Power (Ampl.) Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify) Harmonic Imaging
Ophthalmic										
Fetal										
Abdominal										
Intra-operative - vascular		x	x	x	x	x	x		*	x
Intra-operative Neurological										x
Pediatric										
Small Organ - Thyroid - Breast - Testicle		x	x	x	x	x	x		*	x
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal										
Trans-Rectal										
Trans-Vaginal										
Trans-Urethral										
Intra-Luminal										
Peripheral Vascular		x	x	x	x	x	x		*	x
Laparoscopic										
Musculo-Skeletal Conventional		x	x	x	x	x	x		*	x
Musculo-Skeletal Superficial		x	x	x	x	x	x		*	x
Other (Specify)										

**Additional Comments:**

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

  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal, ENT,  
 and Radiological Devices  
 510(k) Number K97376 7

**Prescription Use** \_\_\_\_\_  
 (Per 21 CFR 801.109)

## Diagnostic Ultrasound Indications for Use Form

**Fill out one form for each ultrasound system and transducer**

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

The 15L8 transducer is intended for Harmonic Imaging and Conventional Contrast Imaging in conjunction with legally marketed contrast agents for the indications that they have been approved".

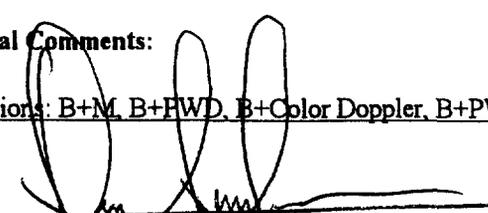
Ultrasound System: Sequoia™

Transducer: 15L8

Clinical Applications	A	B	M	PWD	CWD	Color Doppler	Power (Ampl.) Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify) Harmonic Imaging
Ophthalmic										
Fetal										
Abdominal										
Intra-operative - vascular		x	x	x	x	x	x		*	x
Intra-operative Neurological										
Pediatric										
Small Organ - Thyroid - Breast - Testicle		x	x	x	x	x	x		*	x
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal										
Trans-Rectal										
Trans-Vaginal										
Trans-Urethral										
Intra-Luminal										
Peripheral Vascular		x	x	x	x	x	x		*	x
Laparoscopic										
Musculo-Skeletal Conventional		x	x	x	x	x	x		*	x
Musculo-Skeletal Superficial		x	x	x	x	x	x		*	
Other (Specify)										

Additional Comments:

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

  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal, ENT,  
 and Radiological Devices  
 510(k) Number K973767

Prescription Use \_\_\_\_\_  
 (Per 21 CFR 801.109)

## Diagnostic Ultrasound Indications for Use Form

**Fill out one form for each ultrasound system and transducer**

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

The 8V5 transducer is intended for Harmonic Imaging and Conventional Contrast Imaging in conjunction with legally marketed contrast agents for the indications that they have been approved".

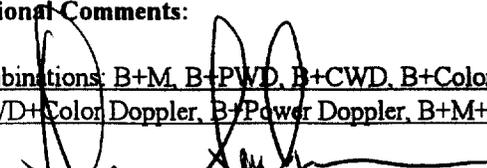
Ultrasound System: Sequoia™

Transducer: 8V5

Clinical Applications	A	B	M	PWD	CWD	Color Doppler	Power (Ampl.) Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify) Hsrmonic Imaging
Ophthalmic										
Fetal		x	x	x	x	x	x		*	x
Abdominal		x	x	x	x	x	x		*	x
Intra-operative (Specify)										
Intra-operative Neurological										
Pediatric		x	x	x	x	x	x		*	x
Small Organ - Thyroid - Breast - Testicle										
Neonatal Cephalic		x	x	x	x	x	x		*	x
Adult Cephalic										
Cardiac		x	x	x	x	x	x		*	x
Trans-esophageal										
Trans-Rectal										
Trans-Vaginal										
Trans-Urethral										
Intra-Luminal										
Peripheral Vascular										
Laparoscopic										
Musculo-Skeletal Conventional										
Musculo-Skeletal Superficial										
Other (Specify)										

**Additional Comments:**

\* Combinations: 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

  
 (Division Sign-Off)

Division of Reproductive, Abdominal, ENT,  
 and Radiological Devices  
 510(k) Number K973707

Prescription Use   
 (Per 21 CFR 801.109)

## Diagnostic Ultrasound Indications for Use Form

**Fill out one form for each ultrasound system and transducer**

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

The 7V3c transducer is intended for Harmonic Imaging and Conventional Contrast Imaging in conjunction with legally marketed contrast agents for the indications that they have been approved".

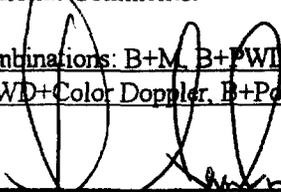
Ultrasound System: Sequoia™

Transducer: 7V3c

Clinical Applications	A	B	M	PWD	CWD	Color Doppler	Power (Ampl.) Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify) Harmonic Imaging
Ophthalmic										
Fetal		x	x	x	x	x	x		*	x
Abdominal		x	x	x	x	x	x		*	x
Intra-operative - abdominal										
Intra-operative Neurological										
Pediatric		x	x	x	x	x	x		*	x
Small Organ - Thyroid - Breast - Testicle										
Neonatal Cephalic		x	x	x	x	x	x		*	x
Adult Cephalic										
Cardiac		x	x	x	x	x	x		*	x
Trans-esophageal										
Trans-Rectal										
Trans-Vaginal										
Trans-Urethral										
Intra-Luminal										
Peripheral Vascular										
Laparoscopic										
Musculo-Skeletal Conventional										
Musculo-Skeletal Superficial										
Other (Specify)										

**Additional Comments:**

\* Combinations: 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

  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal, ENT,  
 and Radiological Devices  
 510(k) Number     K993767    

Prescription Use     ✓      
 (Per 21 CFR 801.109)

## Diagnostic Ultrasound Indications for Use Form

**Fill out one form for each ultrasound system and transducer**

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

The 5V2c transducer is intended for Harmonic Imaging and Conventional Contrast Imaging in conjunction with legally marketed contrast agents for the indications that they have been approved".

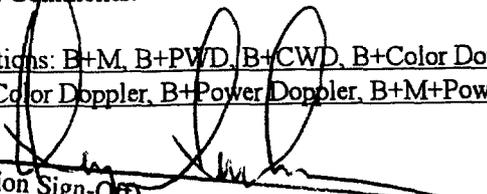
Ultrasound System: Sequoia™

Transducer: 5V2c

Clinical Applications	A	B	M	PWD	CWD	Color Doppler	Power (Ampl.) Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify) Harmonic Imaging
Ophthalmic										
Fetal		x	x	x	x	x	x		*	x
Abdominal		x	x	x	x	x	x		*	x
Intra-operative - cardiac - abdominal										
Intra-operative Neurological										
Pediatric		x	x	x	x	x	x		*	x
Small Organ - Thyroid - Breast - Testicle										
Neonatal Cephalic										
Adult Cephalic										
Cardiac		x	x	x	x	x	x		*	x
Trans-esophageal										
Trans-Rectal										
Trans-Vaginal										
Trans-Urethral										
Intra-Luminal										
Peripheral Vascular										
Laparoscopic										
Musculo-Skeletal Conventional										
Musculo-Skeletal Superficial										
Other (Specify)										

**Additional Comments:**

\* Combinations: 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

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

510(k) Number     K973767    

**Prescription Use**  
 (Per 21 CFR 801.109)

## Diagnostic Ultrasound Indications for Use Form

**Fill out one form for each ultrasound system and transducer**

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

The 3V2c transducer is intended for Harmonic Imaging and Conventional Contrast Imaging in conjunction with legally marketed contrast agents for the indications that they have been approved".

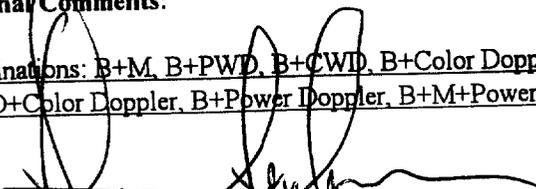
Ultrasound System: Sequoia™

Transducer: 3V2c

Clinical Applications	A	B	M	PWD	CWD	Color Doppler	Power (Ampl.) Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify) Harmonic Imaging
Ophthalmic									*	x
Fetal		x	x	x	x	x	x		*	x
Abdominal		x	x	x	x	x	x			
Intra-operative - abdominal										
Intra-operative Neurological										
Pediatric										
Small Organ - Thyroid - Breast - Testicle										x
Neonatal Cephalic									*	x
Adult Cephalic		x	x	x	x	x	x		*	x
Cardiac		x	x	x	x	x	x		*	x
Trans-esophageal										
Trans-Rectal										
Trans-Vaginal										
Trans-Urethral										
Intra-Luminal										
Peripheral Vascular										
Laparoscopic										
Musculo-Skeletal Conventional										
Musculo-Skeletal Superficial										
Other (Specify)										

**Additional Comments:**

\* Combinations: 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

  
(Division Sign-Off)

Division of Reproductive, Abdominal, ENT, and Radiological Devices

510(k) Number K973767

Prescription Use   
(Per 21 CFR 801.109)



## Diagnostic Ultrasound Indications for Use Form

**Fill out one form for each ultrasound system and transducer**

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

The 5C2 transducer is intended for Harmonic Imaging and Conventional Contrast Imaging in conjunction with legally marketed contrast agents for the indications that they have been approved".

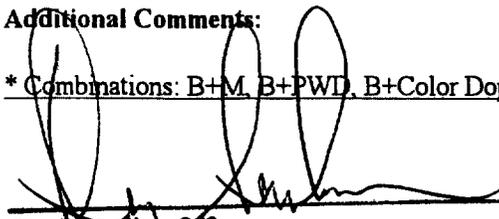
**Ultrasound System:** Sequoia™

**Transducer:** 5C2

Clinical Applications	A	B	M	PWD	CWD	Color Doppler	Power (Ampl.) Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify) Harmonic Imaging
Ophthalmic										
Fetal		x	x	x	x	x	x		*	x
Abdominal		x	x	x	x	x	x		*	x
Intra-operative										
-										
Intra-operative Neurological										
Pediatric		x	x	x	x	x	x		*	x
Small Organ										
- Thyroid										
- Breast										
- Testicle										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal										
Trans-Rectal										
Trans-Vaginal										
Trans-Urethral										
Intra-Luminal										
Peripheral Vascular										
Laparoscopic										
Musculo-Skeletal Conventional										
Musculo-Skeletal Superficial										
Other (Specify)										

**Additional Comments:**

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



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

510(k) Number K973767

Prescription Use   
(Per 21 CFR 801.109)



### Diagnostic Ultrasound Indications for Use Form

**Fill out one form for each ultrasound system and transducer**

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

The EV-8C4 transducer is intended for Harmonic Imaging and Conventional Contrast Imaging in conjunction with legally marketed contrast agents for the indications that they have been approved".

**Ultrasound System:** Sequoia™

**Transducer:** EV-8C4

Clinical Applications	A	B	M	PWD	CWD	Color Doppler	Power (Ampl.) Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify) Harmonic Imaging
Ophthalmic										
Fetal		x	x	x	x	x	x		*	x
Abdominal										
Intra-operative										
Intra-operative										
Neurological										
Pediatric										
Small Organ										
- Thyroid										
- Breast										
- Testicle										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal										
Trans-Rectal										
Trans-Vaginal		x	x	x	x	x	x		*	x
Trans-Urethral										
Intra-Luminal										
Peripheral Vascular										
Laparoscopic										
Musculo-Skeletal Conventional										
Musculo-Skeletal Superficial										
Other (Specify)										

**Additional Comments:**

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

(Division Sign-Off)

Division of Reproductive, Abdominal, ENT, and Radiological Devices

510(k) Number

K973767

Prescription Use   
(Per 21 CFR 801.109)

## Diagnostic Ultrasound Indications for Use Form

**Fill out one form for each ultrasound system and transducer**

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

The Aux CW transducer is intended for Harmonic Imaging and Conventional Contrast Imaging in conjunction with legally marketed contrast agents for the indications that they have been approved".

Ultrasound System: Sequoia™

Transducer: Aux CW

Clinical Applications	A	B	M	PWD	CWD	Color Doppler	Power (Ampl.) Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify) Harmonic Imaging
Ophthalmic										
Fetal										
Abdominal										
Intra-operative (Specify)										
Intra-operative Neurological										
Pediatric		x	x	x	x	x	x		*	x
Small Organ - Thyroid - Breast - Testicle										
Neonatal Cephalic										
Adult Cephalic										
Cardiac		x	x	x	x	x	x			x
Trans-esophageal										
Trans-Rectal										
Trans-Vaginal										
Trans-Urethral										
Intra-Luminal										
Peripheral Vascular										
Laparoscopic										
Musculo-Skeletal Conventional										
Musculo-Skeletal Superficial										
Other (Specify)										

Additional Comments:

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

(Division Sign-Off)

Division of Reproductive, Abdominal, ENT, and Radiological Devices

510(k) Number

K913767

Prescription Use   
(Per 21 CFR 801.109)