

3/22/99

K983879

## 510(k) SUMMARY

This summary statement complies with 21 CFR, section 807.92 as amended March 14, 1995.

This premarket notification has been submitted by Aloka Co., Ltd. and covers the Aloka SSD-900 diagnostic ultrasound system. The address is:

10 Fairfield Boulevard  
Wallingford, CT. 06492

The contact person is Paul D. Smolenski, Manager, Quality and Regulatory Affairs.

The proprietary name for the transducer is the Aloka SSD-900 diagnostic ultrasound system. The common name for this type of device is a diagnostic ultrasound system and associated accessories.

The items in this submission are covered under the following classifications:

- 90 ITX - Transducer, Ultrasonic, Diagnostic
- 90 IYO - Ultrasonic Pulsed Echo Imaging System and Accessories

The above as stated in 21 CFR, part 892.1570, and 892.1560 have been classified as regulatory Class II.

The Aloka SSD-900 is substantially equivalent to several previously marketed diagnostic ultrasound systems such as the Aloka SSD-1400.

The SSD-900 functions in the same manner as other diagnostic ultrasound devices. High frequency sound waves are transmitted into the body by a piezo-electric transducer. In the body, differences in the acoustic impedance of different tissues reflect a certain amount of the ultrasound energy back to the transducer, where it is processed into slice images.

The SSD-900, like other marketed diagnostic ultrasound systems, is indicated for imaging body structures to aid in the diagnosis of disease or abnormality.

The Aloka SSD-900 diagnostic ultrasound system with gray-scale imaging modalities is similar in technological characteristics to ultrasound systems marketed by Aloka and others:

- The SSD-900 is indicated for the same diagnostic ultrasound applications as other products currently marketed by Aloka and others.

- The SSD-900 has the same gray-scale abilities as other products currently offered by Aloka and others.
- The SSD-900 uses essentially the same technologies for imaging and signal processing as other products currently marketed by Aloka and others.
- The SSD-900 has the same method of use as other products currently marketed by Aloka and others.
- The SSD-900 acoustic power output levels are below the maximum levels allowed by the FDA.
- The SSD-900 is subjected to the same Quality Assurance systems in development and production as other products currently marketed by Aloka.
- The patient contact materials used in the probes for the SSD-900 have been evaluated and found to be safe for this application.
- The SSD-900 complies with the same electrical and physical safety standards as other products currently marketed by Aloka.



MAR 22 1999

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Shoichi Nakai  
General Manager  
Aloka Co., Ltd.  
10 Fairfield Boulevard  
Wallingford, CT 06492-7502

Re: K983879  
Aloka SSD-900 Diagnostic Ultrasound System  
Regulatory Class: II/ 21 CFR 892.1560/21 CFR 892.1570  
Product Code: 90 IYO/90 ITX  
Dated: February 1, 1999  
Received: February 2, 1999

Dear Mr. Nakai:

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

This determination of substantial equivalence applies to the following transducers intended for use with the Aloka SSD-900 Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

ASU-35WL-10	ASU-36WL-10	ASU-35-3	ASU-66	ASU-64
UST-5524-7.5	UST-5536-7.5	UST-579T-7.5	UST-670P-5	UST-670P-5
UST-979-3.5	UST-984P-5	UST-987-7.5	UST-9116P-5	UST-995-7.5

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

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

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

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

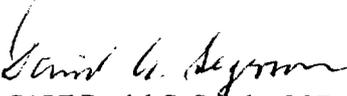
Food and Drug Administration  
Center for Devices and Radiological Health  
Document Mail Center (HFZ-401)  
9200 Corporate Boulevard  
Rockville, Maryland 20850

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

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

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

Sincerely yours,

  
for CAPT Daniel G. Schultz, M.D.  
Acting Director, Division of Reproductive,  
Abdominal, Ear, Nose and Throat,  
and Radiological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosures

**Ultrasound Device Indications Statement**

510(k) Number (if known): unknown at submission  
 Device Name: Aloka SSD-900 Diagnostic Ultrasound System

Fill our one form for each ultrasound system and transducer

Indications for Use: Diagnostic Ultrasound imaging of the human body as follows:

Clinical Application	MODES of OPERATION									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	CVI	Combined	Other
Ophthalmic										
Fetal		✓	✓						B/M	
Abdominal		✓	✓						B/M	
Intra-Operative		✓	✓						B/M	
Intra-Operative Neurological		✓	✓						B/M	
Pediatric		✓	✓						B/M	
Small Organ		✓	✓						B/M	
Neonatal Cephalic		✓	✓						B/M	
Adult Cephalic		✓	✓						B/M	
Cardiac Adult		✓	✓						B/M	
Cardiac Pediatric		✓	✓						B/M	
Transesophageal										
Transrectal		✓	✓						B/M	
Transvaginal		✓	✓						B/M	
Transurethral										
Musculo-Skeletal Conventional		✓	✓						B/M	
Musculo-skeletal Superficial										
Intraluminal										
Peripheral Vessel		✓	✓						B/M	
Laparoscopic		✓	✓						B/M	

Other Indications or Modes:

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (O

Prescription Use (Per 21 CFR 801.109)

*David G. Segerson*  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal, ENT,  
 and Radiological Devices  
 510(k) Number K983879

**Ultrasound Device Indications Statement**

510(k) Number (if known): unknown at submission  
 Device Name: ASU-35WL-10

Fill our one form for each ultrasound system and transducer

Indications for Use: Diagnostic Ultrasound imaging of the human body as follows:

Clinical Application	MODES of OPERATION									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	CVI	Combined	Other
Ophthalmic										
Fetal										
Abdominal										
Intra-Operative										
Intra-Operative										
Neurological										
Pediatric										
Small Organ		✓	✓							
Neonatal Cephalic										
Adult Cephalic										
Cardiac Adult										
Cardiac Pediatric										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Musculo-Skeletal Conventional										
Musculo-skeletal Superficial										
Intraluminal										
Peripheral Vessel										
Laparoscopic										

Other Indications or Modes:

Small Organ Applications: Breast, Testes, Thyroid

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

*David G. Segman*  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal, ENT,  
 and Radiological Devices

Prescription Use (Per 21 CFR 801.109)

510(k) Number K983879

K983879

Ultrasound Device Indications Statement

510(k) Number (if known): unknown at submission
Device Name: ASU-36WL-10

Fill our one form for each ultrasound system and transducer

Indications for Use: Diagnostic Ultrasound imaging of the human body as follows:

Table with columns: Clinical Application, A, B, M, PWD, CWD, Color Doppler, Amplitude Doppler, CVI, Combined, Other. Rows include Ophthalmic, Fetal, Abdominal, Intra-Operative, Neurological, Pediatric, Small Organ, Neonatal Cephalic, Adult Cephalic, Cardiac Adult, Cardiac Pediatric, Transesophageal, Transrectal, Transvaginal, Transurethral, Musculo-Skeletal Conventional, Musculo-skeletal Superficial, Intraluminal, Peripheral Vessel, Laparoscopic.

Other Indications or Modes:

Small Organ Applications: Breast, Testes, Thyroid

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Segerson
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K983879

Prescription Use (Per 21 CFR 801.109)

Ultrasound Device Indications Statement

510(k) Number (if known): unknown at submission  
 Device Name: ASU-35-3

Fill our one form for each ultrasound system and transducer

Indications for Use: Diagnostic Ultrasound imaging of the human body as follows:

Clinical Application	MODES of OPERATION									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	CVI	Combined	Other
Ophthalmic										
Fetal										
Abdominal										
Intra-Operative										
Intra-Operative Neurological										
Pediatric										
Small Organ		✓	✓							
Neonatal Cephalic										
Adult Cephalic										
Cardiac Adult		✓	✓							
Cardiac Pediatric		✓	✓							
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Musculo-Skeletal Conventional										
Musculo-skeletal Superficial										
Intraluminal										
Peripheral Vessel										
Laparoscopic										

Other Indications or Modes:

Small Parts: Breast, Testes, Thyroid

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

*David G. Bergman*  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal, ENT,  
 and Radiological Devices  
 510(k) Number K983879

Prescription Use (Per 21 CFR 801.109)

Ultrasound Device Indications Statement

510(k) Number (if known): unknown at submission  
 Device Name: ASU-66

Fill our one form for each ultrasound system and transducer

Indications for Use: Diagnostic Ultrasound imaging of the human body as follows:

Clinical Application	MODES of OPERATION									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	CVI	Combined	Other
Ophthalmic										
Fetal		✓	✓							
Abdominal										
Intra-Operative										
Intra-Operative Neurological										
Pediatric										
Small Organ										
Neonatal Cephalic										
Adult Cephalic										
Cardiac Adult										
Cardiac Pediatric										
Transesophageal										
Transrectal										
Transvaginal		✓	✓							
Transurethral										
Musculo-Skeletal Conventional										
Musculo-skeletal Superficial										
Intraluminal										
Peripheral Vessel										
Laparoscopic										

Other Indications or Modes:

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

*David C. Segerson*  
 (Division Sign-Off)

Division of Reproductive, Abdominal, ENT, and Radiological Devices

510(k) Number K983879

Prescription Use (Per 21 CFR 801.109)

K983879

**Ultrasound Device Indications Statement**

510(k) Number (if known): unknown at submission  
 Device Name: ASU-64

Fill our one form for each ultrasound system and transducer

Indications for Use: Diagnostic Ultrasound imaging of the human body as follows:

Clinical Application	MODES of OPERATION									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	CVI	Combined	Other
Ophthalmic										
Fetal										
Abdominal										
Intra-Operative										
Intra-Operative										
Neurological										
Pediatric										
Small Organ										
Neonatal Cephalic										
Adult Cephalic										
Cardiac Adult										
Cardiac Pediatric										
Transesophageal										
Transrectal		✓	✓							
Transvaginal										
Transurethral										
Musculo-Skeletal Conventional										
Musculo-skeletal Superficial										
Intraluminal										
Peripheral Vessel										
Laparoscopic										

Other Indications or Modes:

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

*David G. Segman*  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal, ENT,  
 and Radiological Devices  
 510(k) Number K983879

Prescription Use (Per 21 CFR 801.109)

K983879

Ultrasound Device Indications Statement

510(k) Number (if known): unknown at submission  
 Device Name: UST-5524-7.5

Fill our one form for each ultrasound system and transducer

Indications for Use: Diagnostic Ultrasound imaging of the human body as follows:

Clinical Application	MODES of OPERATION									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	CVI	Combined	Other
Ophthalmic										
Fetal										
Abdominal										
Intra-Operative										
Intra-Operative										
Neurological										
Pediatric										
Small Organ		✓	✓						B/M	
Neonatal Cephalic										
Adult Cephalic										
Cardiac Adult										
Cardiac Pediatric										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Musculo-Skeletal Conventional										
Musculo-skeletal Superficial										
Intraluminal										
Peripheral Vessel		✓	✓						B/M	
Laparoscopic										

Other Indications or Modes:

Small Organ Applications: Breast, Testes, Thyroid

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

*David G. [Signature]*  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal, ENT,  
 and Radiological Devices

Prescription Use (Per 21 CFR 801.109)

510(k) Number K983879

**Ultrasound Device Indications Statement**

510(k) Number (if known): unknown at submission  
 Device Name: UST-5536-7.5 Transducer

Fill out one form for each ultrasound system and transducer

Indications for Use: Diagnostic Ultrasound imaging of the human body as follows:

Clinical Application	MODES of OPERATION									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	CVI	Combined	Other
Ophthalmic										
Fetal										
Abdominal										
Intra-Operative										
Intra-Operative										
Neurological										
Pediatric										
Small Organ										
Neonatal Cephalic										
Adult Cephalic										
Cardiac Adult										
Cardiac Pediatric										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Musculo-Skeletal Conventional										
Musculo-skeletal Superficial										
Intraluminal										
Peripheral Vessel										
Laparoscopic		✓	✓						B/M	

Other Indications or Modes:

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

*David G. Siegman*  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal, ENT,  
 and Radiological Devices  
 510(k) Number K983879

Prescription Use (Per 21 CFR 801.109)

Ultrasound Device Indications Statement

510(k) Number (if known): unknown at submission  
 Device Name: UST-579T-7.5

Fill our one form for each ultrasound system and transducer

Indications for Use: Diagnostic Ultrasound imaging of the human body as follows:

Clinical Application	MODES of OPERATION									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	CVI	Combined	Other
Ophthalmic										
Fetal										
Abdominal										
Intra-Operative		✓	✓						B/M	
Intra-Operative Neurological										
Pediatric										
Small Organ		✓	✓						B/M	
Neonatal Cephalic										
Adult Cephalic										
Cardiac Adult										
Cardiac Pediatric										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Musculo-Skeletal Conventional										
Musculo-skeletal Superficial										
Intraluminal										
Peripheral Vessel		✓	✓						B/M	
Laparoscopic										

Combined Modes: B/M, B/PWD

Other Indications or Modes:

Intraoperative Applications: Abdominal (such as liver, pancreas, gall bladder)

Small Organ Applications: Breast, Testes, Thyroid

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

*David W. Seymour*  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal, ENT,  
 and Radiological Devices  
 510(k) Number K983879

Prescription Use (Per 21 CFR 801.109)

Ultrasound Device Indications Statement

510(k) Number (if known): unknown at submission  
 Device Name: UST-672-5/7.5

Fill our one form for each ultrasound system and transducer

Indications for Use: Diagnostic Ultrasound imaging of the human body as follows:

Clinical Application	MODES of OPERATION									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	CVI	Combined	Other
Ophthalmic										
Fetal										
Abdominal										
Intra-Operative		✓	✓						B/M	
Intra-Operative Neurological										
Pediatric										
Small Organ										
Neonatal Cephalic										
Adult Cephalic										
Cardiac Adult										
Cardiac Pediatric										
Transesophageal										
Transrectal		✓	✓						B/M	
Transvaginal										
Transurethral										
Musculo-Skeletal Conventional										
Musculo-skeletal Superficial										
Intraluminal										
Peripheral Vessel										
Laparoscopic										

Other Indications or Modes:

Intraoperative Applications: Abdominal (such as liver, pancreas, gall bladder)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

*David C. Keyser*  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal, ENT,  
 and Radiological Devices  
 510(k) Number K983879

Prescription Use (Per 21 CFR 801.109)

K983879

**Ultrasound Device Indications Statement**

510(k) Number (if known): unknown at submission  
 Device Name: UST-670P-5

Fill our one form for each ultrasound system and transducer

Indications for Use: Diagnostic Ultrasound imaging of the human body as follows:

Clinical Application	MODES of OPERATION									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	CVI	Combined	Other
Ophthalmic										
Fetal										
Abdominal										
Intra-Operative										
Intra-Operative Neurological										
Pediatric										
Small Organ										
Neonatal Cephalic										
Adult Cephalic										
Cardiac Adult										
Cardiac Pediatric										
Transesophageal										
Transrectal		✓	✓						B/M	
Transvaginal		✓	✓						B/M	
Transurethral										
Musculo-Skeletal Conventional										
Musculo-skeletal Superficial										
Intraluminal										
Peripheral Vessel										
Laparoscopic										

Other Indications or Modes:

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

*[Signature]*  
 (Division Sign-Off)

Division of Reproductive, Abdominal, ENT, and Radiological Devices

Description Use (Per 21 CFR 801.109)

510(k) Number K983879

K983879

Ultrasound Device Indications Statement

510(k) Number (if known): unknown at submission

Device Name: UST-979-3.5

Fill our one form for each ultrasound system and transducer

Indications for Use: Diagnostic Ultrasound imaging of the human body as follows:

Clinical Application	MODES of OPERATION									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	CVI	Combined	Other
Ophthalmic										
Fetal		✓	✓						B/M	
Abdominal		✓	✓						B/M	
Intra-Operative										
Intra-Operative Neurological										
Pediatric		✓	✓						B/M	
Small Organ										
Neonatal Cephalic										
Adult Cephalic										
Cardiac Adult										
Cardiac Pediatric										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Musculo-Skeletal Conventional										
Musculo-skeletal Superficial										
Intraluminal										
Peripheral Vessel										
Laparoscopic										

Other Indications or Modes:

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

*David A. Segerson*  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal, ENT,  
 and Radiological Devices  
 510(k) Number K983879

Description Use (Per 21 CFR 801.109)

K983879

Ultrasound Device Indications Statement

510(k) Number (if known): unknown at submission  
 Device Name: UST-984P-5

Fill our one form for each ultrasound system and transducer

Indications for Use: Diagnostic Ultrasound imaging of the human body as follows:

Clinical Application	MODES of OPERATION									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	CVI	Combined	Other
Ophthalmic										
Fetal		✓	✓						B/M	
Abdominal										
Intra-Operative										
Intra-Operative										
Neurological										
Pediatric										
Small Organ										
Neonatal Cephalic										
Adult Cephalic										
Cardiac Adult										
Cardiac Pediatric										
Transesophageal										
Transrectal										
Transvaginal		✓	✓						B/M	
Transurethral										
Musculo-Skeletal Conventional										
Musculo-skeletal Superficial										
Intraluminal										
Peripheral Vessel										
Laparoscopic										

Other Indications or Modes:

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

*David A. Seymour*  
 (DIVISION SIGN-OFF)  
 DIVISION of Reproductive, Abdominal, ENT,  
 and Radiological Devices  
 510(k) Number K983879

Prescription Use (Per 21 CFR 801.109)

K983879

Ultrasound Device Indications Statement

510(k) Number (if known): unknown at submission  
 Device Name: UST-987-7.5

Fill our one form for each ultrasound system and transducer

Indications for Use: Diagnostic Ultrasound imaging of the human body as follows:

Clinical Application	MODES of OPERATION									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	CVI	Combined	Other
Ophthalmic										
Fetal										
Abdominal										
Intra-Operative		✓	✓						B/M	
Intra-Operative		✓	✓						B/M	
Neurological										
Pediatric										
Small Organ		✓	✓						B/M	
Neonatal Cephalic		✓	✓						B/M	
Adult Cephalic										
Cardiac Adult										
Cardiac Pediatric										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Musculo-Skeletal Conventional										
Musculo-skeletal Superficial										
Intraluminal										
Peripheral Vessel										
Laparoscopic										

Other Indications or Modes:

Intraoperative Applications: Neurological, Abdominal (such as liver, pancreas, gall bladder)  
 Small Organ Applications: Breast, Testes, Thyroid

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

*David G. Ferguson*  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal, ENT,  
 and Radiological Devices

510(k) Number K983879

Prescription Use (Per 21 CFR 801.109)

**Ultrasound Device Indications Statement**

510(k) Number (if known): unknown at submission  
 Device Name: UST-9116P-5

Fill out one form for each ultrasound system and transducer

Indications for Use: Diagnostic Ultrasound imaging of the human body as follows:

Clinical Application	MODES of OPERATION									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	CVI	Combined	Other
Ophthalmic										
Fetal										
Abdominal										
Intra-Operative		✓	✓						B/M	
Intra-Operative		✓	✓						B/M	
Neurological										
Pediatric										
Small Organ										
Neonatal Cephalic										
Adult Cephalic										
Cardiac Adult										
Cardiac Pediatric										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Musculo-Skeletal Conventional										
Musculo-skeletal Superficial										
Intraluminal										
Peripheral Vessel										
Laparoscopic										

Other Indications or Modes:

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

*David A. Legman*  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal, ENT,  
 and Radiological Devices  
 510(k) Number K983879

Description Use (Per 21 CFR 801.109)

Ultrasound Device Indications Statement

510(k) Number (if known): unknown at submission  
 Device Name: UST-995-7.5

Fill our one form for each ultrasound system and transducer

Indications for Use: Diagnostic Ultrasound imaging of the human body as follows:

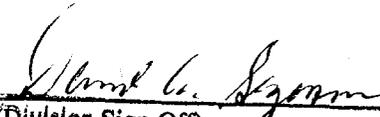
Clinical Application	MODES of OPERATION									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	CVI	Combined	Other
Ophthalmic										
Fetal										
Abdominal										
Intra-Operative		✓	✓						B/M	
Intra-Operative Neurological										
Pediatric										
Small Organ										
Neonatal Cephalic										
Adult Cephalic										
Cardiac Adult										
Cardiac Pediatric										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Musculo-Skeletal Conventional										
Musculo-skeletal Superficial										
Intraluminal										
Peripheral Vessel										
Laparoscopic										

Combined Modes: B/M,B/PWD  
 Other Indications or Modes:

Intraoperative Applications: Abdominal (such as liver, pancreas, gall bladder)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED.)

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