

K 972465
P. 1 of 2

AUG 15 1997

1. 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-1400 diagnostic ultrasound system and associated transducers. The address is:

10 Fairfield Boulevard
Wallingford, CT. 06492

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

The proprietary name is the Aloka SSD-1400 diagnostic ultrasound system. The common name for this type of device is a diagnostic ultrasound system.

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

- 90 IYN - System, Imaging, Pulsed Doppler, Ultrasonic
- 90 IYO - System, Imaging, Pulsed Echo, Ultrasonic
- 90 ITX - Transducer, Ultrasonic, Diagnostic

The above as stated in 21 CFR, part 892.1550, 892.1560 and 892.1570, have been classified as regulatory Class II.

The Aloka SSD-1400 is substantially equivalent to the Aloka SSD-1700 and Aloka Omniview diagnostic ultrasound systems and transducers. The Aloka SSD-1700 was originally cleared for market via the 510(k) process in 1997, the Omniview was cleared in 1996.

The Aloka SSD-1400 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 an image. The Aloka SSD-1400 can also use the Doppler shift of sound reflected from moving tissues (blood) to detect and display flow.

The Aloka SSD-1400, like other marketed diagnostic ultrasound systems, is indicated for imaging body structures to aid in the diagnosis of disease or abnormality.

The Aloka SSD-1400 diagnostic ultrasound system with gray-scale and Doppler imaging modalities is similar in technological characteristics to ultrasound systems marketed by Aloka and others:

- The SSD-1400 is indicated for the same diagnostic ultrasound applications as other products currently marketed by Aloka and others.
- The SSD-1400 has the same gray-scale and Doppler abilities as other products currently offered by Aloka and others.
- The SSD-1400 uses essentially the same technologies for imaging, Doppler functions and signal processing as other products currently marketed by Aloka and others.
- The SSD-1400 has the same method of use as other products currently marketed by Aloka and others.
- The SSD-1400 acoustic power output levels are below the maximum levels allowed by the FDA.
- The SSD-1400 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-1400 have been evaluated and found to be safe for this application.
- The SSD-1400 complies with the same electrical and physical safety standards as other products currently marketed by Aloka.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 15 1997

Paul D. Smolenski
Manager, Quality and Regulatory Affairs
ALOKA Co., Inc.
10 Fairfield Boulevard
Wallingford, CT 06492-7502

Re: K972465
ALOKA SSD-1400 Diagnostic
Ultrasound System
Dated: June 30, 1997
Received: July 1, 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. Smolenski:

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 (Act). You may, therefore, market the device, subject to the general controls provisions 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 ALOKA SSD-1400 Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

ASU-35WL-10	ASU-66	UST-2266-5	UST-5524-7.5
UST-5536-7.5	UST-579T-7.5	UST-672-5/7.5	UST-670P-5
UST-979-3.5	UST-984P-5	UST-978-7.5	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 regulation (CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. *Please note:* this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 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.

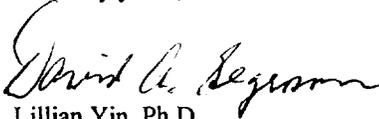
Page 2 - Mr. Paul Smolenski

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 
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(s)

Ultrasound Device Indications Statement

510(k) Number (if known): unknown at submission **K972465**
 Device Name: Aloka SSD-1400 Diagnostic Ultrasound System

Fill our one form for each ultrasound system and transducer

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

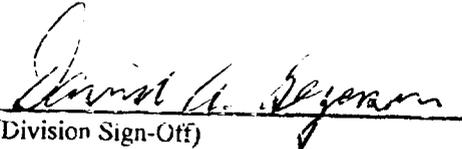
Clinical Application	MODES of OPERATION									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	CVI	Combined	Other
Ophthalmic										
Fetal		✓	✓	✓					See Below	
Abdominal		✓	✓	✓					See Below	
Intra-Operative		✓	✓	✓					See Below	
Intra-Operative		✓	✓	✓					See Below	
Neurological										
Pediatric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

Combined Modes: B/M, B/PWD

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)


 (Division Sign-Off)
 Division of Reproductive, Abdominal, ENT,
 and Radiological Devices
 510(k) Number K972465

Prescription Use (Per 21 CFR 801.109)

Ultrasound Device Indications Statement

510(k) Number (if known): unknown at submission **K972465**
 Device Name: ASU-35WL-10

Fill our one form for each ultrasound system and transducer

- Indications for Use: Diagnostic Ultrasound imaging and Doppler analysis of the human body as follows:

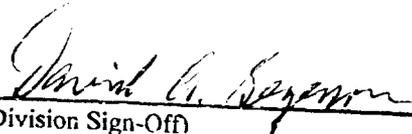
Clinical Application	MODES of OPERATION									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	CVI	Combined	Other
Ophthalmic										
Fetal										
Abdominal										
Intra-Operative										
Intra-Operative Neurological										
Pediatric										
Small Organ		✓	✓						B/M	
Neonatal Cephalic										
Adult Cephalic										
Cardiac Adult										
Cardiac Pediatric										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
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)


 (Division Sign-Off)
 Division of Reproductive, Abdominal, ENT,
 and Radiological Devices
 510(k) Number K972465

Prescription Use (Per 21 CFR 801.109)

Ultrasound Device Indications Statement

510(k) Number (if known): unknown at submission **K972465**
 Device Name: ASU-66

Fill our one form for each ultrasound system and transducer

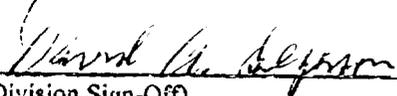
Indications for Use: Diagnostic Ultrasound imaging and Doppler analysis of the human body as follows:

Clinical Application	MODES of OPERATION									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	CVI	Combined	Other
Ophthalmic										
Fetal		✓	✓	✓					B/M, B/PWD	
Abdominal										
Intra-Operative										
Intra-Operative										
Neurological										
Pediatric										
Small Organ										
Neonatal Cephalic										
Adult Cephalic										
Cardiac Adult										
Cardiac Pediatric										
Transesophageal										
insrectal										
Transvaginal		✓	✓	✓					B/M, B/PWD	
Transurethral										
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)



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

Prescription Use (Per 21 CFR 801.109)

510(k) Number K972465

Ultrasound Device Indications Statement

§10(k) Number (if known): unknown at submission
 Device Name: UST-2266-5

K972465

Fill our one form for each ultrasound system and transducer

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

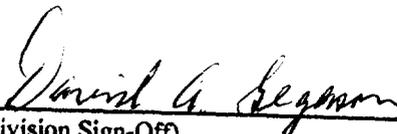
Clinical Application	MODES of OPERATION									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	CVI	Combined	Other
Ophthalmic										
Fetal										
Abdominal										
Intra-Operative										
Intra-Operative Neurological										
Pediatric										
Small Organ										
Neonatal Cephalic										
Adult Cephalic										
Cardiac Adult					✓					
Cardiac Pediatric					✓					
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
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)

Prescription Use (Per 21 CFR 801.109)


 (Division Sign-Off)
 Division of Reproductive, Abdominal, ENT,
 and Radiological Devices
 §10(k) Number K972465

Ultrasound Device Indications Statement

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

K972465

Fill our one form for each ultrasound system and transducer

Indications for Use: Diagnostic Ultrasound imaging and Doppler analysis 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		✓	✓	✓					See Below	
Neonatal Cephalic										
Adult Cephalic										
Cardiac Adult										
Cardiac Pediatric										
Transesophageal										
nsrectal										
Transvaginal										
Transurethral										
Intraluminal										
Peripheral Vessel		✓	✓	✓					See Below	
Laparoscopic										

Combined Modes: B/M, B/PWD

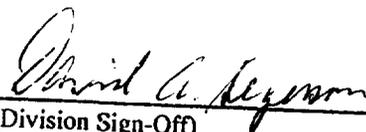
Other Indications or Modes:

Small Organ Applications: Breast, Testes, Thyroid

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)


 (Division Sign-Off)
 Division of Reproductive, Abdominal, ENT,
 and Radiological Devices
 510(k) Number K972465

Ultrasound Device Indications Statement

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

K972465

Fill our one form for each ultrasound system and transducer

Indications for Use: Diagnostic Ultrasound imaging and Doppler analysis 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										
nsrectal										
Transvaginal										
Transurethral										
Intraluminal										
Peripheral Vessel										
Laparoscopic		✓	✓	✓					See Below	

Combined Modes: B/M, B/PWD

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. Bejerman

 (Division Sign-Off)

Division of Reproductive, Abdominal, ENT,
 and Radiological Devices

510(k) Number K972465

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

K972465

Fill our one form for each ultrasound system and transducer

Indications for Use: Diagnostic Ultrasound imaging and Doppler analysis 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		✓	✓	✓					See Below	
Intra-Operative Neurological										
Pediatric										
Small Organ		✓	✓	✓					See Below	
Neonatal Cephalic										
Adult Cephalic										
Cardiac Adult										
Cardiac Pediatric										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intraluminal										
Peripheral Vessel		✓	✓	✓					See Below	
Laparoscopic										

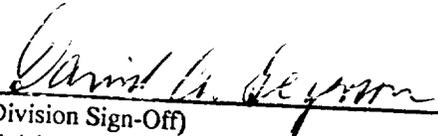
Combined Modes: B/M, B/PWD
 Other Indications or Modes:

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)

Prescription Use (Per 21 CFR 801.109)


 (Division Sign-Off)
 Division of Reproductive, Abdominal, ENT,
 and Radiological Devices
 510(k) Number K972465

Ultrasound Device Indications Statement

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

K972465

Fill out one form for each ultrasound system and transducer

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

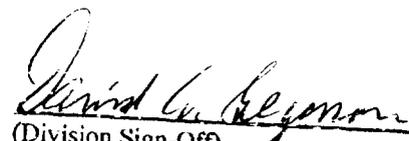
Clinical Application	MODES of OPERATION									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	CVI	Combined	Other
Ophthalmic										
Fetal										
Abdominal										
Intra-Operative		✓	✓	✓					See Below	
Intra-Operative Neurological										
Pediatric										
Small Organ										
Neonatal Cephalic										
Adult Cephalic										
Cardiac Adult										
Cardiac Pediatric										
Transesophageal										
nsrectal		✓	✓	✓					See Below	
ransvaginal										
Transurethral										
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.)

Concurrence of CDRE, Office of Device Evaluation (ODE)


 (Division Sign-Off)
 Division of Reproductive, Abdominal, ENT,
 and Radiological Devices
 510(k) Number K972465

Prescription Use (Per 21 CFR 801.109)

Ultrasound Device Indications Statement

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

K972465

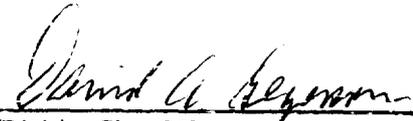
Fill our one form for each ultrasound system and transducer

Indications for Use: Diagnostic Ultrasound imaging and Doppler analysis 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		✓	✓	✓					See Below	
transvaginal										
Transurethral										
Intraluminal										
Peripheral Vessel										
Laparoscopic										

Combined Modes: B/M, B/PWD
 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)


 (Division Sign-Off)
 Division of Reproductive, Abdominal, ENT,
 and Radiological Devices
 510(k) Number K972465

Prescription Use (Per 21 CFR 801.109)

Ultrasound Device Indications Statement

510(k) Number (if known): unknown at submission
 Device Name: UST-979-3.5

K972465

Fill our one form for each ultrasound system and transducer

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

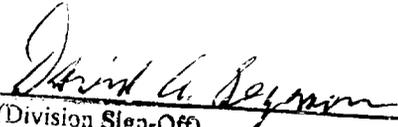
Clinical Application	MODES of OPERATION									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	CVI	Combined	Other
Ophthalmic										
Fetal		✓	✓	✓					See Below	
Abdominal		✓	✓	✓					See Below	
Intra-Operative										
Intra-Operative Neurological										
Pediatric		✓	✓	✓					See Below	
Small Organ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

Combined Modes: B/M, B/PWD

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)


 (Division Sign-Off)
 Division of Reproductive, Abdominal, ENT,
 and Radiological Devices
 510(k) Number K972465

Prescription Use (Per 21 CFR 801.109)

Ultrasound Device Indications Statement

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

K972465

Fill our one form for each ultrasound system and transducer

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

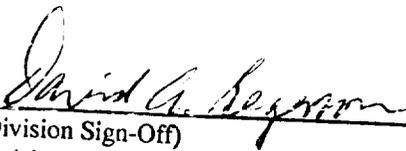
Clinical Application	MODES of OPERATION									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	CVI	Combined	Other
Ophthalmic										
Fetal		✓	✓	✓					See Below	
Abdominal										
Intra-Operative										
Intra-Operative Neurological										
Pediatric										
Small Organ										
Neonatal Cephalic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

Combined Modes: B/M, B/PWD
 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)

Prescription Use (Per 21 CFR 801.109)


 (Division Sign-Off)
 Division of Reproductive, Abdominal, ENT,
 and Radiological Devices
 510(k) Number K972465

Ultrasound Device Indications Statement

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

K972465

Fill our one form for each ultrasound system and transducer

Indications for Use: Diagnostic Ultrasound imaging and Doppler analysis 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		✓	✓	✓					See Below	
Intra-Operative		✓	✓	✓					See Below	
Neurological										
Pediatric										
Small Organ		✓	✓	✓					See Below	
Neonatal Cephalic		✓	✓	✓					See Below	
Adult Cephalic										
Cardiac Adult										
Cardiac Pediatric										
Transesophageal										
Anorectal										
Transvaginal										
Transurethral										
Intraluminal										
Peripheral Vessel										
Laparoscopic										

Combined Modes: B/M, B/PWD

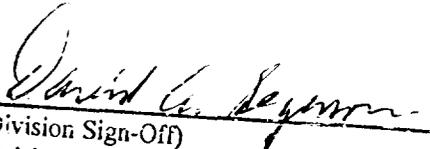
Other Indications or Modes:

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)


 (Division Sign-Off)
 Division of Reproductive, Abdominal, ENT,
 and Radiological Devices
 510(k) Number K972465

Prescription Use (Per 21 CFR 801.109)

Ultrasound Device Indications Statement

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

K972465

Fill out one form for each ultrasound system and transducer

- Indications for Use: Diagnostic Ultrasound imaging and Doppler analysis 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		✓	✓	✓					See Below	
Intra-Operative										
Neurological										
Pediatric										
Small Organ		✓	✓	✓					See Below	
Neonatal Cephalic										
Adult Cephalic										
Cardiac Adult										
Cardiac Pediatric										
Transesophageal										
unsrectal										
Transvaginal										
Transurethral										
Intraluminal										
Peripheral Vessel		✓	✓	✓					See Below	
Laparoscopic										

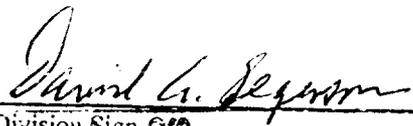
Combined Modes: B/M,B/PWD

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.)

Concurrence of CDRH, Office of Device Evaluation (ODE)



 (Division Sign-Off)
 Division of Reproductive, Abdominal, ENT,
 and Radiological Devices
 510(k) Number K972465

Prescription Use (Per 21 CFR 801.109)