

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-5500 diagnostic ultrasound system. The address is:

Aloka Co., Ltd.
10 Fairfield Boulevard
Wallingford, CT. 06492

The contact person is Christopher M. Bohl, Technical Product Manager.

The proprietary name for the system is the Aloka SSD-5500 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 IYN - Ultrasonic, Pulsed Doppler Imaging System
- 90 ITX - Transducer, Ultrasonic, Diagnostic
- 90 IYO - Ultrasonic Pulsed Echo Imaging System and Accessories

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

The Aloka SSD-5500 is substantially equivalent to several previously marketed diagnostic ultrasound systems such as the Aloka SSD-2000, Aloka SSD-1700, Toshiba PowerVision, H.P. Sonos 5500, Vingmed (G.E.) System V and ATL HDI-5000

The SSD-5500 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 two-dimensional images. The reflected ultrasound energy is also processed using Doppler principals and displays moving blood as a spectrum or as a color-coded real time two-dimensional image.

The SSD-5500, like other marketed diagnostic ultrasound systems, is indicated for imaging body structures and flowing blood to aid in the diagnosis of disease or abnormality.

The Aloka SSD-5500 diagnostic ultrasound system with gray-scale, spectral Doppler and color flow mapping imaging modes is similar in technological characteristics to ultrasound systems marketed by Aloka and others:

- The SSD-5500 is indicated for the same diagnostic ultrasound applications as other products currently marketed by Aloka and others.
- The SSD-5500 has the same gray-scale, spectral Doppler and Color Flow Mapping abilities as other products currently offered by Aloka and others.

- The SSD-5500 uses similar technologies for imaging and signal processing as other products currently marketed by Aloka and others.
- The SSD-5500 has the same method of use as other products currently marketed by Aloka and others.
- The SSD-5500 acoustic power output levels are below the maximum levels allowed by the FDA.
- Aloka subjects the SSD-5500 to the same Quality Assurance systems in development and production as other products currently marketed.
- The patient contact materials used in the probes for the SSD-5500 have been evaluated and found to be safe for their intended application.
- The SSD-5500 complies with the same electrical and physical safety standards as other products currently marketed by Aloka.

4.2 BASIC INFORMATION

4.2.1 Manufacturer's Name

The Aloka SSD-5500 manufactured by:

Aloka Co., Ltd.
6-22-1 Mure, Mitaka-shi
Tokyo 181 Japan

4.2.2 Initial Distributor

The initial distributor for Aloka products is:

Aloka Co., Ltd.
10 Fairfield Blvd.
Wallingford, CT 06492

4.2.3 Device Name

The name of the device is the Aloka SSD-5500 diagnostic ultrasound system.

4.2.4 Common Name

The SSD-5500 is commonly known as a diagnostic ultrasound system.

4.2.5 Classification

The Aloka SSD-5500 may be classified as 90 IYO-Ultrasonic Pulsed Imaging System and 90 IYN-Ultrasonic Pulsed Doppler Imaging System. The associated transducers are classified as 90 ITX - Diagnostic Ultrasound Transducer.

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

4.2.6 Establishment Registration Number

The establishment registration number for Aloka America is 1222669

4.2.7 514 Performance Standards

There are no 514-performance standards for diagnostic ultrasound equipment.

4.2.8 Special Controls

Special controls for diagnostic ultrasound consist of the "Special Controls Report" consisting primarily of final acoustic output and final labeling. The Special Controls report for the product described in this submission will be submitted at a future date and prior to first customer shipment.

4.2.9 Prescription Status

All diagnostic ultrasound systems are prescription devices. The prescription statement appears in the user's manuals.

4.2.10 Manufacturing Location

Aloka in Japan manufactures the SSD-5500.

4.2.11 Sterilization Site

None of the products described in this submission are provided sterile.

4.2.12 Reason for Submission

The SSD-5500 is a new diagnostic ultrasound system.

4.2.13 Track (1 or 3)

The SSD-5500 is a Track 3 system.

4.3 INDICATIONS FOR USE

4.3.1 INDICATIONS FOR USE OF THE SSD-5500

The subject Aloka SSD-5500 is an all-digital diagnostic ultrasonic scanner with a digital beamformer supporting gray scale, spectral Doppler and Color Flow imaging. It is based upon and substantially equivalent to the Aloka SSD-1700 and SSD-2000 systems, which received clearance for market under K963616 and K954022. The SSD-5500 is also equivalent to other high performance digital beamforming systems such as the Toshiba PowerVision, ATL HDI-5000, H.P. Sonos 5500 and Vingmed (G.E.) System V.

The Aloka SSD-5500 is a Track 3 system. Its maximum acoustic outputs are below the pre-amendments upper limits and it conforms to the "Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment". The maximum thermal index is below 6.0. Depending on the probe, the Aloka SSD-5500 may be used for diagnostic ultrasound imaging in Cardiac, Gynecological, Neurological, Obstetrical, Neonatal, Pediatric, Perinatal, Radiological, Vascular, Urological, Trauma and Surgical applications.

The Aloka SSD-5500 is not indicated for ophthalmic applications and there are no other contraindication known.



AUG 24 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850Aloka Co., Ltd.
C/o Donald J. Sherratt
Intertek Testing Services
70 Codman Hill Road
Boxborough, MA 01719Re: K992663
Aloka SSD 5500
Dated: August 6, 1999
Received: August 9, 1999
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. Sherratt:

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 5500, as described in your premarket notification:

Transducer Model Number

UST-5268P-5	UST-5286-2.5
UST-5536-7.5	UST-5539-7.5
UST-5713T	UST-672-5/7.5
UST-675P	UST-9119
UST-987-7.5	UST-995-7.5
UST-9118	

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

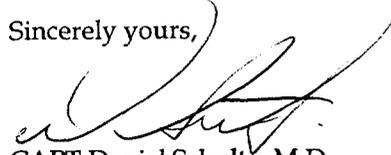
This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

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- Mr. Sherratt

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

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Daniel Schultz', written over a horizontal line.

CAPT Daniel 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

Diagnostic Ultrasound Indications for Use Form
SSD-5500

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

Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		√	√	√		√	√		See Below	
Abdominal		√	√	√		√	√		See Below	
Intraoperative (specify)		√	√	√		√	√		See Below	
Intraoperative Neurological		√	√	√		√	√		See Below	
Pediatric		√	√	√		√	√		See Below	
Small Organ (specify)		√	√	√		√	√		See Below	
Neonatal Cephalic		√	√	√		√	√		See Below	
Adult Cephalic		√	√	√		√	√		See Below	
Cardiac		√	√	√	√	√	√		See Below	
Transesophageal		√	√	√		√	√		See Below	
Transrectal		√	√	√		√	√		See Below	
Transvaginal		√	√	√		√	√		See Below	
Transurethral										
Intravascular										
Peripheral Vascular		√	√	√		√	√		See Below	
Laparoscopic		√	√	√		√	√		See Below	
Musculo-skeletal Conventional		√	√	√		√	√		See Below	
Musculo-skeletal Superficial										
Other										

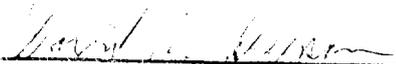
N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Mixed mode operation includes B/M, B/PWD, B/Bflow/PWD. Intraoperative applications include liver, pancreas and gall bladder. Small parts applications include breast, testes and 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 K992663

Diagnostic Ultrasound Indications for Use Form
UST-5268P-5

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

Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)		√	√	√		√	√		See Below	
Intraoperative Neurological		√	√	√		√	√		See Below	
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic		√	√	√		√	√		See Below	
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other										

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

Additional Comments: Combined mode operation includes B/M, B/PWD, B/Bflow/PWD. The transducer has applications in Neurological Burr Hole and abdominal surgical applications such liver, pancreas and gall bladder.

(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 K992663

Diagnostic Ultrasound Indications for Use Form
UST-5286-2.5

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

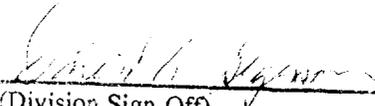
Clinical Application	Modes of operation										
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)	
Ophthalmic											
Fetal											
Abdominal											
Intraoperative (specify)											
Intraoperative Neurological											
Pediatric											
Small Organ (specify)											
Neonatal Cephalic											
Adult Cephalic											
Cardiac		√	√	√	√	√	√		See Below		
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular											
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other											

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

Additional Comments: Mixed mode operation includes B/M, B/PWD, B/Bflow/PWD.

(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 K992663

Diagnostic Ultrasound Indications for Use Form
UST-5536-7.5

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

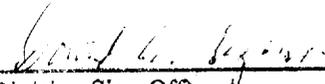
Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic		√	√	√		√	√		See Below	
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other										

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

Additional Comments: Mixed mode operation includes B/M, B/PWD, B/Bflow/PWD

(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 K992663

Diagnostic Ultrasound Indications for Use Form
UST-5539-7.5

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

Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)		√	√	√		√	√		See Below	
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		√	√	√		√	√		See Below	
Laparoscopic										
Musculo-skeletal Conventional		√	√	√		√	√		See Below	
Musculo-skeletal Superficial										
Other										

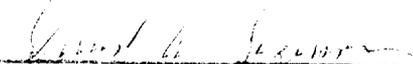
N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Mixed mode operation includes B/M, B/PWD, B/Bflow/PWD. Small Parts applications include Breast, Testes and 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 K992663

Diagnostic Ultrasound Indications for Use Form
UST-5713T

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

Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	O (sp
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)		√	√	√		√	√		See Below	
Intraoperative Neurological										
Pediatric										
Small Organ (specify)		√	√	√		√	√		See Below	
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional		√	√	√		√	√		See Below	
Musculo-skeletal Superficial										
Other										

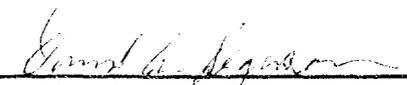
N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Mixed mode operation includes B/M, B/PWD, B/Bflow/PWD. Intraoperative applications for this transducer include liver, pancreas and gall bladder. Small Organ applications include breast, testes and 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 K992663

Diagnostic Ultrasound Indications for Use Form
UST-672-5/7.5

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

Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)		√	√	√		√	√		See Below	
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal		√	√	√		√	√		See Below	
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other										

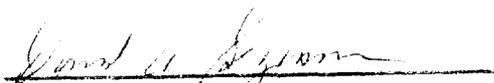
N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Mixed mode operation includes B/M, B/PWD, B/Bflow/PWD. Intraoperative applications include abdominal, bladder, pancreas and gall bladder.

(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 K992663

Diagnostic Ultrasound Indications for Use Form
UST-675P

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

Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal		√	√	√		√	√		See Below	
Transvaginal		√	√	√		√	√		See Below	
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other										

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

Additional Comments: Mixed mode operation includes B/M, B/PWD, B/Bflow/PWD.

(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 K992663

Diagnostic Ultrasound Indications for Use Form
UST-9118

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

Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		√	√	√		√	√		See Below	
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal		√	√	√		√	√		See Below	
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other										

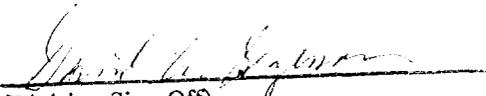
N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Mixed mode operation includes B/M, B/PWD, B/Bflow/PWD.

(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

Diagnostic Ultrasound Indications for Use Form
UST-9119

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

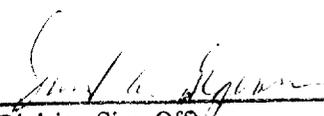
Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		√	√	√		√	√		See Below	
Abdominal		√	√	√		√	√		See Below	
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other		√	√	√		√	√		See Below	

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

Additional Comments: Mixed mode operation includes B/M, B/PWD, B/Bflow/PWD. The Other application of this transducer is in gynecological imaging of the female pelvis, uterus and ovaries.

(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 K992663

Diagnostic Ultrasound Indications for Use Form
UST-987-7.5

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

Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)		√	√	√		√	√		See Below	
Intraoperative Neurological										
Pediatric										
Small Organ (specify)		√	√	√		√	√		See Below	
Neonatal Cephalic		√	√	√		√	√		See Below	
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		√	√	√		√	√		See Below	
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other										

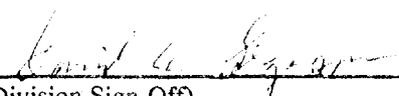
N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Mixed mode operation includes B/M, B/PWD, B/Bflow/PWD. Intraoperative applications for this transducer include liver, pancreas and gall bladder. Small Organ applications include breast, testes and 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 K992663

Diagnostic Ultrasound Indications for Use Form
UST-995-7.5

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

Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)		√	√	√		√	√		See Below	
Intraoperative Neurological										
Pediatric										
Small Organ (specify)		√	√	√		√	√		See Below	
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		√	√	√		√	√		See Below	
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other										

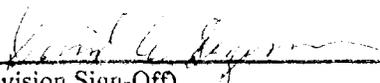
N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Mixed mode operation includes B/M, B/PWD, B/Bflow/PWD. Intraoperative applications for this transducer include liver, pancreas and gall bladder. Small Organ applications include breast, testes and 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 K992663