AUG 2 9 2001

K012080

510(k) Summary

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

Submitter's Name and Address

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

Contact's Name, Title, Address and Telephone Number

Kelvin Burroughs
Regulatory Affairs/Quality Assurance Coordinator
Aloka Co., Ltd.
10 Fairfield Boulevard
Wallingford, CT 06492
(203) 269-5088

Device Proprietary Name

SSD-5000 Diagnostic Ultrasound System

Device Common Name

Diagnostic ultrasound system

Classification

The charts below list the Regulatory Class and Device Codes.

Subject	Description
Regulatory Class	Class II
Review Category	Tier II

Code	Description	Regulation
90 ITX	Transducer, Ultrasonic, Diagnostic	892.1570
90 IYN	Ultrasonic, Pulsed Doppler Imaging System	892.1550
90 IYO	Ultrasonic, Pulsed Echo Imaging System and Accessories	892.1560

Continued on next page

510(k) Summary, Continued

Identification of predicate devices	The SSD-5000 is substantially equivalent to the SSD-5500, which is subject of the following submitted and cleared 510(k)s: K992663, K002784, K011315 and K011457.
Device Description	The SSD-5000 makes no changes to the indications for use, the ultrasound generator, transducer(s), controls, or signal processing technologies. There are no new system functions, significant new clinical information provided or significant claims of added effectiveness. In addition, clinical applications/modes of operation provide no new significant interpretation of the predicate device, the SSD-5500.
Probes	Probe that are the subject of a submitted and cleared 510(k) for the SSD-5500 have already been added to the SSD-5000. New probes and additional probes for used with the SSD-5000 are the subjects of this submission.
Intended Use	The SSD-5000 Diagnostic Ultrasound System and Transducers be used for diagnostic ultrasound imaging in Cardiac, Gynecological, Neurological, Obstetrical, Neonatal, Pediatric, Perinatal, Radiological, Vascular, Urological, Abdominal, Gastrointestinal, Trauma, Surgical and Endoscopic applications. The Aloka SSD-5500 is not indicated for ophthalmic applications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 9 2001

Mr. Kelvin Burroughs
Coordinator, Regulatory Affairs & Quality Assurance
ALOKA Co., Ltd.
10 Fairfield Boulevard
WALLINGFORD CT 06492-7502

Re: K012080
Trade Name: Aloka SSD-5000 Diagnostic Ultrasound System
Regulatory Class: II/21 CFR 892.1550
Product Code: 90 IYN
Regulatory Class: II/21 CFR 892.1560
Product code: 90 IYO
Dated: June 29, 2001
Received: July 3, 2001

Dear Mr. Burroughs:

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-5000 Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

ASU-67
ASU-1000C-3.5
ASU-1002
UST-2265-2
UST-5271S-5

UST-5281-5
UST-5284-2.5
UST-5285-3.5
UST-5293-5
UST-5294-5
UST-5296
UST-5297
UST-5524-5
UST-5524-7.5
UST-5531
UST-5534T-7.5
UST-5543
UST-5545
UST-5712
UST-9101-7.5
UST-9104-5
UST-9114-3.5
UST-9115-5

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.

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, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

Diagnostic Ultrasound Indications for Use Form

System/Transducer	System
Model	SSD-5000
510(k) Number	Appendix E

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)
Opthalmic										
Fetal		E	E	E	E	E	E		See Below	
Abdominal		E	E	E		E	E		See Below	
Intraoperative (specify)		E	E	E		E	E		See Below	
Intraoperative Neurological		E	E	E	E	E	E		See Below	
Pediatric		E	E	E		E	E		See Below	
Small Organ (specify)		E	E	E		E	E		See Below	
Neonatal Cephalic		E	E	E		E	E		See Below	
Adult Cephalic										
Cardiac		E	E	E	E	E	E		See Below	
Transesophageal		E	E	E	E	E	E		See Below	
Transrectal		E	E	E		E	E		See Below	
Transvaginal		E	E	E		E	E		See Below	
Transurethral										
Intravascular										
Peripheral Vascular		E	E	E		E	E		See Below	
Laparoscopic		E	E	E		E	E		See Below	
Musculo-skeletal Conventional		E	E	E		E	E		See Below	
Musculo-skeletal Superficial		E	E	E		E	E		See Below	
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/CD, M/CD, B/CD/PWD, B/A-SMA.

(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)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K012080

Diagnostic Ultrasound Indications for Use Form

System/Transducer	Transducer
Model	ASU-67
510(k) Number	Appendix E

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)
Opthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal		E	E	E		E	E		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/CD, M/CD, B/CD/PWD, B/A-SMA.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K012080

Diagnostic Ultrasound Indications for Use Form

System/Transducer	Transducer
Model	ASU-1000C-3.5
510(k) Number	Appendix E

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)
Opthalmic										
Fetal		E	E	E		E	E		See Below	
Abdominal		E	E	E		E	E		See Below	
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal		E	E	E		E	E		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/CD, M/CD, B/CD/PWD, B/A-SMA.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K012080

Diagnostic Ultrasound Indications for Use Form

System/Transducer	Transducer
Model	ASU-1002
510(k) Number	Appendix E

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)
Opthalmic										
Fetal		E	E	E		E	E		See Below	
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal		E	E	E		E	E		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/CD, M/CD, B/CD/PWD, B/A-SMA.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K012080

Diagnostic Ultrasound Indications for Use Form

System/Transducer	Transducer
Model	UST-2265-2
510(k) Number	K941652

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)
Opthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac					P					
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/CD, M/CD, B/CD/PWD, B/A-SMA.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K012080

Diagnostic Ultrasound Indications for Use Form

System/Transducer	Transducer
Model	UST-5271S-5
510(k) Number	Appendix E

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)
Opthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		E	E	E		E	E		See Below	
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac		E	E	E		E	E		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/CD, M/CD, B/CD/PWD, B/A-SMA.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K012080

Diagnostic Ultrasound Indications for Use Form

System/Transducer	Transducer
Model	UST-5281-5
510(k) Number	Appendix E

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)
Opthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological		E	E	E	E	E	E		See Below	
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac		E	E	E	E	E	E		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/CD, M/CD, B/CD/PWD, B/A-SMA.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K012080

Diagnostic Ultrasound Indications for Use Form

System/Transducer	Transducer
Model	UST-5284-2.5
510(k) Number	

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)
Opthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac		N	N	N	N	N	N		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/CD, M/CD, B/CD/PWD, B/A-SMA.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K012080

Diagnostic Ultrasound Indications for Use Form

System/Transducer	Transducer
Model	UST-5285-3.5
510(k) Number	

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)
Opthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac		N	N	N	N	N	N		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/CD, M/CD, B/CD/PWD, B/A-SMA.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Nancy C. Brogdon

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

K012080

Diagnostic Ultrasound Indications for Use Form

System/Transducer	Transducer
Model	UST-5293-5
510(k) Number	K003739

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)
Opthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac		P	P	P	P	P	P		See Below	
Transesophageal		P	P	P	P	P	P		See Below	
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/CD, M/CD, B/CD/PWD, B/A-SMA.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K012080

Diagnostic Ultrasound Indications for Use Form

System/Transducer	Transducer
Model	UST-5294-5
510(k) Number	Appendix E

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)**
Opthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac		E	E	E	E	E	E		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/CD, M/CD, B/A-SMA.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K012080

Diagnostic Ultrasound Indications for Use Form

System/Transducer	Transducer
Model	UST-5296
510(k) Number	Appendix E

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)
Opthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		E	E	E		E	E		See Below	
Small Organ (specify)										
Neonatal Cephalic		E	E	E		E	E		See Below	
Adult Cephalic										
Cardiac		E	E	E	E	E	E		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/CD, M/CD, B/CD/PWD,

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K012080

Diagnostic Ultrasound Indications for Use Form

System/Transducer	Transducer
Model	UST-5297
510(k) Number	

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)
Opthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac		N	N	N	N	N	N		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/CD, M/CD, B/CD/PWD, B/A-SMA.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Nancy C. Brogdon

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

K012080

Diagnostic Ultrasound Indications for Use Form

System/Transducer	Transducer
Model	UST-5524-5
510(k) Number	K983879

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)
Opthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)		P	P	P		P	P		See Below	
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		P	P	P		P	P		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/CD, M/CD.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
(Division Sign-Off) Number K012080

Diagnostic Ultrasound Indications for Use Form

System/Transducer	Transducer
Model	UST-5524-7.5
510(k) Number	Appendix E

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)
Opthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)		E	E	E		E	E		See Below	
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		E	E	E		E	E		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/CD, M/CD.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K012080

Diagnostic Ultrasound Indications for Use Form

System/Transducer	Transducer
Model	UST-5531
510(k) Number	K941652

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)
Opthalmic										
Fetal										
Abdominal										
Intraoperative (specify)		P	P	P		P	P		See Below	
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										

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

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K012080

Diagnostic Ultrasound Indications for Use Form

System/Transducer	Transducer
Model	UST-5534T-7.5
510(k) Number	K963616

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)
Opthalmic										
Fetal										
Abdominal										
Intraoperative (specify)		P	P	P		P	P		See Below	
Intraoperative Neurological										
Pediatric										
Small Organ (specify)		P	P	P		P	P		See Below	
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		P	P	P		P	P		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/CD, M/CD.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109) Nancy C. Brogdon

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Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K012080

Diagnostic Ultrasound Indications for Use Form

System/Transducer	Transducer
Model	UST-5543
510(k) Number	Appendix E

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)**
Opthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)		E	E	E		E	E		See Below	
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		E	E	E		E	E		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/CD, M/CD, B/CD/PWD.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

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and Radiological D
510(k) Number K012080

Diagnostic Ultrasound Indications for Use Form

System/Transducer	Transducer
Model	UST-5545
510(k) Number	Appendix E

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)
Opthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)		E	E	E		E	E		See Below	
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		E	E	E		E	E		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/CD, M/CD.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K012080

Diagnostic Ultrasound Indications for Use Form

System/Transducer	Transducer
Model	UST-5712
510(k) Number	Appendix E

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)
Opthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)		E	E	E		E	E		See Below	
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		E	E	E		E	E		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/CD, M/CD.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Nancy C. Brogdon

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and Radiological Devices
510(k) Number K012080

Diagnostic Ultrasound Indications for Use Form

System/Transducer	Transducer
Model	UST-9101-7.5
510(k) Number	K963616

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)
Opthalmic										
Fetal										
Abdominal		P	P	P		P	P		See Below	
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		P	P	P		P	P		See Below	
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
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: Mixed mode operation includes B/M, B/PWD, B/CD, M/CD, B/CD/PWD.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K012080

Diagnostic Ultrasound Indications for Use Form

System/Transducer	Transducer
Model	UST-9104-5
510(k) Number	K900805

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)
Opthalmic										
Fetal										
Abdominal										
Intraoperative (specify)		P	P	P		P	P		See Below	
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic		P	P	P		P	P		See Below	
Adult Cephalic										
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: Mixed mode operation includes B/M, B/PWD, B/CD, M/CD.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K012080

Diagnostic Ultrasound Indications for Use Form

System/Transducer	Transducer
Model	UST-9114-3.5
510(k) Number	Appendix E

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)
Opthalmic										
Fetal		E	E	E		E	E		See Below	
Abdominal		E	E	E		E	E		See Below	
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal		E	E	E		E	E		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/CD, M/CD, B/CD/PWD.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Nancy C. Brogdon

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Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K012080

Diagnostic Ultrasound Indications for Use Form

System/Transducer	Transducer
Model	UST-9115-5
510(k) Number	Appendix E

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)
Opthalmic										
Fetal										
Abdominal		E	E	E		E	E		See Below	
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		E	E	E		E	E		See Below	
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
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: Mixed mode operation includes B/M, B/PWD, B/CD, M/CD, B/CD/PWD.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K012080