JUL 1 0 2002

K020468

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

ASU-1003
UST-9121
UST-9124

Device Common Name

Diagnostic Ultrasound Transducers

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

Continued on next page

510(k) Summary, Continued

Identification of predicate devices

The following is a list of probes submitted in this notification, their predicate devices and the 510(k) clearance numbers.

Subject Transducer	Predicate Transducer	Predicate Transducer 510(k)/Appendix E
ASU-1003	ASU-1000C-3.5	K012253
UST-9121	UST-9114-3.5	K012080
UST-9124	UST-9103-5	K012253

Probes

Probes that are the subject of a submitted and cleared 510(k) for the SSD-1400 have already been added to the SSD-1000. New and additional probes for used with the SSD-1000 are the subjects of this submission.

Intended Use

The transducers are to be used for diagnostic ultrasound imaging in Urological, Abdominal, Intraoperative, Surgical and Endoscopic applications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 1 0 2002

Mr. Richard J. Cehovsky
Regulatory Affairs/Quality Assurance
ALOKA Co., Ltd. U.S.A.
10 Fairfield Boulevard
WALLINGFORD CT 06492-7502

Re: K020668
Trade Name: Aloka SSD-1000 Diagnostic Ultrasound System
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasound pulsed echo imaging system
Regulation Number: 21 CFR 892.1570
Regulaton Name: Diagnostic ultrasound transducer
Regulatory Class: II
Product Code: 90 IYO and ITX
Dated: May 8, 2002
Received: May 9, 2002

Dear Mr. Cehovsky:

We have reviewed your Section 510(k) premarket 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-1000, as described in your premarket notification:

Transducer Model Number

ASU-1003
UST-9121
UST-9124

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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, 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 Part 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
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-1000
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						See Below	
Abdominal		E	E						See Below	
Intraoperative (specify)		E	E						See Below	
Intraoperative Neurological		E	E						See Below	
Pediatric		E	E						See Below	
Small Organ (specify)		E	E						See Below	
Neonatal Cephalic		E	E						See Below	
Adult Cephalic		E	E						See Below	
Cardiac		E	E						See Below	
Transesophageal										
Transrectal		E	E						See Below	
Transvaginal		E	E						See Below	
Transurethral										
Intravascular										
Peripheral Vascular		E	E						See Below	
Laparoscopic		E	E						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-Mode

(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 K020668

Diagnostic Ultrasound Indications for Use Form

System/Transducer	Transducer
Model	ASU-1003
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		N	N						See Below	
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal		N	N						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.

(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 K020668

Diagnostic Ultrasound Indications for Use Form

System/Transducer	Transducer
Model	UST-9121
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		P	P						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										

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

Additional Comments: Mixed mode operation includes B/M

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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 K020668

Diagnostic Ultrasound Indications for Use Form

System/Transducer	Transducer
Model	UST-9124
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		P	P						See Below	
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal		P	P						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.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

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