JUL 3 0 2004

Section 4.2.13b

510(k) Summary of S&E

(Immediately follows this page)

Date: 6/8/04

510(k) Summary: Aloka Model SSD- Alpha 5

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-Alpha 5 Ver.1.0 diagnostic ultrasound system and transducers.
The address is:

10 Fairfield Boulevard
Wallingford, CT 06492
(203) 269-5088

The contact person is: Richard J. Cehovsky, RA/QA Coordinator

The proprietary name is the Aloka SSD-Alpha 5 diagnostic ultrasound system and transducers. The common name for this type of device is a diagnostic ultrasound system and transducers.

The item in this submission is covered under the following classification:

90 IYN	Ultrasonic Pulsed Doppler Imaging System	21 CFR 892.1550
90 ITX	Diagnostic Ultrasound Transducer	21 CFR 892.1570
90 IYO	Ultrasonic Pulsed Echo Imaging System.	21 CFR 892.1560

The above as stated in 21CFR, part 892.1570,1560 & 1550, has been classified as regulatory Class II.

The Aloka SSD- Alpha 5 and its transducers are substantially equivalent to its predicate; the Aloka SSD-5500 (K032875) and its transducers.
The Aloka SSD-Alpha 5 functions in the same manner as its predicate and other Aloka 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 transmitted via the probe cable to the system console and processed into an image. The Aloka SSD-Alpha 5 transducers can also use the Doppler shift of sound reflected from moving tissues (blood) to detect and display flow.

The Aloka SSD-Alpha 5, like other Aloka marketed diagnostic ultrasound systems and transducers are indicated for imaging body structures to aid in the diagnosis of disease or abnormality.

The Aloka SSD-Alpha 5 diagnostic ultrasound system and transducers are similar in technological characteristics to its predicate system: SSD-5500 (K032875).

- The Aloka SSD-Alpha 5 is indicated for the same diagnostic ultrasound applications to Aloka's ultrasound system: SSD-5500 (K032875).
- The Aloka SSD-Alpha 5 has the same gray-scale and Doppler abilities to Aloka's ultrasound system as mentioned above.

510(k) Summary: Aloka Model SSD- Alpha 5

- The SSD-Alpha 5 uses the same technologies for imaging, Doppler functions and signal processing as the following product currently marketed by Aloka : SSD-5500 (K032875).
- The SSD-Alpha 5 has the same method of use as the following product currently marketed by Aloka: SSD-5500 (K032875).
- The SSD-Alpha 5 acoustic power output levels are below the maximum levels allowed by the FDA.
- The SSD- Alpha 5 is subjected to the same Quality Assurance systems in development and production as other products including the SSD-5500 (K032875) currently marketed by Aloka.
- The patient contact materials used in the SSD-Alpha 5 have been evaluated for safety via the same standards and methods as the above mentioned product marketed by Aloka.These materials have been found to be safe for their intended uses.
- The SSD-Alpha 5 complies with electrical and physical safety standards as other products currently marketed by Aloka such as the: SSD-5500 (K032875).
- Aloka Co., Ltd. Certifies that the SSD-Alpha 5 complies with NEMA-UD2: 1992, AIUM 1994 "Acoustic Output Labeling Standard for Diagnostic Ultrasound Equipment", IEC-60601-1 (2001-09 Class A), UL 2601-1, 2nd edition (1997), Part 1, 2nd edition including Amendments 1&2 and ISO10993-1:1997. All testing will be completed, prior to distribution, to meet the requirements of the standards listed above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 3 0 2004

Aloka Co., Ltd.
% Mr. Daniel W. Lehtonen
Staff Engineer - Medical Devices
Intertek Testing Services NA, Inc.
70 Codman Hill Road
BOXBOROUGH MA 01719

Re: K041916
Trade Name: Aloka SSD-Alpha 5 Ultrasound System
Regulation Number: 21 CFR §892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulation Number: 21 CFR §892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulation Number: 21 CFR §892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: II
Product Code: 90 IYN, IYO, and ITX
Dated: July 15, 2004
Received: July 16, 2004

Dear Mr. Lehtonen:

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-Alpha 5 Ultrasound System, as described in your premarket notification:

Transducer Model Number

UST-5410	UST-9128
UST-9118	UST-52101
UST-9126	UST-52108

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,

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

Enclosures

4.3.1

Diagnostic Ultrasound Indications for Use Form
SSD-Alpha 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)
Opthalmic										
Fetal		N	N	N	N	N	N		See Below	
Abdominal		N	N	N	N	N	N		See Below	
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		N	N	N	N	N	N		See Below	
Small Organ (specify)		N	N	N	N	N	N		See Below	
Neonatal Cephalic		N	N	N	N	N	N		See Below	
Adult Cephalic										
Cardiac		N	N	N	N	N	N		See Below	
Transesophageal										
Transrectal										
Transvaginal		N	N	N	N	N	N		See Below	
Transurethral										
Intravascular										
Peripheral Vascular		N	N	N	N	N	N		See Below	
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial		N	N	N	N	N	N		See Below	
Other										

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

Additional Comments: Mixed mode operation includes B/M, B/PWD, M/CD, B/CD/PWD, B/CWD, B/CD/CWD
Applications: Small Parts-breast, testes & thyroid, abdominal, gynecological, fetal, neonatal, cardiac.

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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 K041916

Diagnostic Ultrasound Indications for Use Form
UST- 5410

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)		N	N	N	N	N	N		See Below	
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		N	N	N	N	N	N		See Below	
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial		N	N	N	N	N	N		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, M/CD, B/CD/PWD, B/CWD, B/CD/CWD

Applications: breast, testes and thyroid.

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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 K041916

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

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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 K041916

Diagnostic Ultrasound Indications for Use Form
UST- 9126

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	P	P	P	P		See Below	
Abdominal		P	P	P	P	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, B/PWD, M/CD, B/CD/PWD, B/CWD, B/CD/CWD.

Applications: Abdominal, Gynecological, Fetal.

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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 K074916

Diagnostic Ultrasound Indications for Use Form
UST- 9128

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	P		See Below	
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		P	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, M/CD, B/CD/PWD, B/CWD, B/CD/CWD

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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 K041916

Diagnostic Ultrasound Indications for Use Form
UST- 52101

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										
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, M/CD, B/CD/PWD, B/CWD, B/CD/CWD

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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 K041916

Diagnostic Ultrasound Indications for Use Form
UST- 52108

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		P	P	P	P	P	P		See Below	
Adult Cephalic										
Cardiac		P	P	P	P	P	P		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, M/CD, B/CD/PWD, B/CWD, B/CD/CWD

Application: Neonatal

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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 K041916