MAR 18 1998

1. 510(k) SUMMARY

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

This premarket notification has been submitted by Aloka Co., Ltd. and covers the Aloka ASU-1000 transducer and associated Volume Mode 3-D rendering software. The address is:

10 Fairfield Boulevard
Wallingford, CT. 06492

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

The proprietary name for the transducer is the Aloka ASU-1000 diagnostic ultrasound transducer. The 3-D rendering software is "Volume Mode". The common name for this type of device is a diagnostic ultrasound transducer and associated accessories.

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

90 ITX - Transducer, Ultrasonic, Diagnostic
90 IYN - Ultrasonic pulsed Doppler system and accessories

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

The Aloka ASU-1000 and Volume mode software are substantially equivalent to several previously marketed 3-D rendering systems for ultrasound including the TomTek Echo-Scan system.

The ASU-1000 and Volume mode software can be used on the Aloka SSD-1700 and SSD-1400 diagnostic ultrasound systems. These systems function 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 slice images. The slice images are processed by the Volume Mode software into a 3-D surface rendering of the target tissues.

The ASU-1000 and Volume mode software, like other marketed diagnostic ultrasound systems and 3-D rendering packages, is indicated for imaging body structures in two and three dimensions to aid in the diagnosis of disease or abnormality.

- The ASU-1000 and Volume mode software are indicated for the same diagnostic ultrasound applications as other products currently marketed.
- The ASU-1000 and Volume mode software have the same gray-scale and Doppler abilities as other products currently offered by Aloka and others.
- The ASU-1000 and Volume mode software have the same 3-D rendering abilities as products currently available.
- The ASU-1000 and Volume mode software uses essentially the same technologies for imaging, Doppler functions and signal processing as other products currently marketed by Aloka and others.
- The ASU-1000 and Volume mode have similar methods of use as other products currently marketed by Aloka and others.
- The ASU-1000 acoustic power output levels are below the maximum levels allowed by the FDA.
- The ASU-1000 and Volume mode software are subjected to the same Quality Assurance systems in development and production as other products currently marketed by Aloka.
- The patient contact material used in the ASU-1000 has been evaluated and found to be safe for this application.
- The ASU-1000 and Volume mode software complies with the same electrical and physical safety standards as other products currently marketed by Aloka.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 18 1998

Paul D. Smolenski
Manager, Quality and Regulatory Affairs
Aloka Co., Ltd.
10 Fairfield Blvd.
Wallingford, CT 06492

Re: K974544
Aloka ASU-1000 Diagnostic Ultrasound Transducer
Dated: March 5, 1997
Received: March 6 1997
Regulatory Class: II
21 CFR 892.1570/Procode: 90 ITX

Dear Mr. Smolenski:

We have reviewed your section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug and Cosmetic Act. You may, therefore, market the device, subject to the general controls provisions Act (Act). The general controls provisions of the Act include requirements for registration, listing of devices, good manufacturing practices, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the Aloka ASU-1000 Diagnostic Ultrasound Transducers intended for use with the following diagnostic ultrasound systems, as described in your premarket notification:

System Model Number

Aloka SSD-1700
Aloka SSD-1400

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

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

Sincerely yours,

for

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

K974544

Ultrasound Device Indications Statement

510(k) Number (if known): unknown at submission
Device Name: **ASU-1000 with Volume Mode 3-D Software**
System: **SSD-1400**

Fill our one form for each ultrasound system and transducer

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

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

Combined Modes: B/M, B/PWD
Other Indications or Modes:3-D rendering of fetal and maternal structures in Obstetrics.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED.)
Concurrence of CDRH, Office of Device Evaluatition (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K974544

K974544

Ultrasound Device Indications Statement

510(k) Number (if known): unknown at submission
Device Name: **ASU-1000 with Volume Mode 3-D Software**
System: **SSD-1700**

Fill our one form for each ultrasound system and transducer

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

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

Combined Modes: B/M, B/PWD, M/CD, B/PWD/CD
Other Indications or Modes:3-D rendering of fetal and maternal structures in Obstetrics.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluatition (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K974544

Prescription Use (Per 21 CFR 801.109)