

1. 510(k) SUMMARY

JUN - 3 1997

K964549

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 UST-5258-5 diagnostic ultrasound transducer. The address is:

10 Fairfield Boulevard
Wallingford, CT 06492

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

The proprietary name is the Aloka UST-5258-5 diagnostic ultrasound transducer. The common name for this type of device is a diagnostic ultrasound transducer.

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

90 ITX - Transducer, Ultrasonic, Diagnostic

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

The Aloka UST-5258-5 is substantially equivalent to the Aloka UST-5228-5 diagnostic ultrasound transducer.

The Aloka UST-5258-5 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 transmitted via the probe cable to the system console and processed into an image. The Aloka UST-5258-5 transducer can also use the Doppler shift of sound reflected from moving tissues (blood) to detect and display flow.

The Aloka UST-5258-5, like other marketed diagnostic ultrasound transducers, is indicated for imaging body structures to aid in the diagnosis of disease or abnormality.

The Aloka UST-5258-5 diagnostic ultrasound transducer is similar in technological characteristics to ultrasound transducers marketed by Aloka and others:

- The UST-5258-5 is indicated for the same diagnostic ultrasound applications as other products currently marketed by Aloka and others.

- The UST-5258-5 has the same gray-scale and Doppler abilities as other products currently offered by Aloka and others.
- The UST-5258-5 uses essentially the same technologies for imaging, Doppler functions and signal processing as other products currently marketed by Aloka and others.
- The UST-5258-5 has the same method of use as other products currently marketed by Aloka and others.
- The UST-5258-5 acoustic power output levels are below the maximum levels allowed by the FDA.
- The UST-5258-5 is subjected to the same Quality Assurance systems in development and production as other products currently marketed by Aloka.
- The patient contact materials used in the UST-5258-5 have been evaluated for safety via the same standards and methods as other products marketed by Aloka and others. These materials have been found to be safe for the intended uses.
- The UST-5258-5 complies with the same electrical and physical safety standards as other products currently marketed by Aloka and others.



JUN - 3 1997

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Paul D. Smolenski
Manager, Quality and Regulatory Affairs
Aloka Company, LTD.
10 Fairfield Blvd.
Wallingford, CT 06492-7502

Re: K964549
ALOKA UST-5258 Diagnostic
Ultrasound Transducer
Dated: March 12, 1997
Received: March 13, 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 following transducer intended for use with the SSD-1700 as described in your premarket notification:

Transducer Model Number

5 MHZ UST-5258

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 for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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.

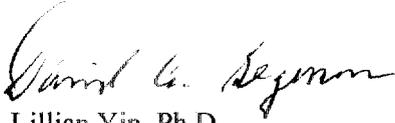
This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

Page 2 - Mr. Paul Smolenski

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 Maureen Butler 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

Indications for Use Summary

Device Name: Aloka UST-5258-5 Diagnostic Ultrasound Transducer
 510(k) Number: Unknown at time of submission

Intended Use: Diagnostic ultrasound imaging and Doppler analysis of the human body.
 Medical disciplines that use transesophageal diagnostic ultrasound include Cardiology,
 Surgery and Trauma.

Clinical Applications	Modes of Operation							
	A	B	M	PWD	CWD	Color Flow Mapping	Combined	Other
Ophthalmic								
Fetal								
Abdominal								
Small Organ								
Cardiac		✓	✓	✓		✓	B/M, B/PWD, M/CFM, B/CFM/PWD	
Peripheral Vessel								
Other*		✓	✓	✓		✓	B/M, B/PWD, M/CFM, B/CFM/PWD	

*Intraoperative, Trauma.

David A. Bejerman
 (Division Sign-Off)
 Division of Reproductive, Abdominal, ENT,
 and Radiological Devices
 510(k) Number 1K964549

Prescription Use
 (Per 21 CFR 801.109)