

K963616

APR -3 1997

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 SSD-1700 diagnostic ultrasound system and associated transducers. 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 SSD-1700 diagnostic ultrasound system. The common name for this type of device is a diagnostic ultrasound system.

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

- 90 IYN - System, Imaging, Pulsed Doppler, Ultrasonic
- 90 IYO - System, Imaging, Pulsed Echo, Ultrasonic
- 90 ITX - Transducer, Ultrasonic, Diagnostic

The above as stated in 21 CFR, part 892.1550, 892.1560 and 892.1570, have been classified as regulatory Class II.

The Aloka SSD-1700 is substantially equivalent to the Aloka Omniview diagnostic ultrasound system and transducers. The Aloka Omniview was originally cleared for market via the 510(k) process in 1996.

The Aloka SSD-1700 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 processed into an image. The Aloka SSD-1700 can also use the Doppler shift of sound reflected from moving tissues (blood) to detect and display flow.

The Aloka SSD-1700, like other marketed diagnostic ultrasound systems, is indicated for imaging body structures to aid in the diagnosis of disease or abnormality.

The Aloka SSD-1700 diagnostic ultrasound system with gray-scale and Doppler imaging modalities is similar in technological characteristics to ultrasound systems marketed by Aloka and others:

- The SSD-1700 is indicated for the same diagnostic ultrasound applications as other products currently marketed by ALOKA and others.
- The SSD-1700 has the same gray-scale and Doppler abilities as other products currently offered by ALOKA and others.
- The SSD-1700 uses essentially the same technologies for imaging, Doppler functions and signal processing as other products currently marketed by ALOKA and others.
- The SSD-1700 has the same method of use as other products currently marketed by ALOKA and others.
- The SSD-1700 acoustic power output levels are below the maximum levels allowed by the FDA.
- The SSD-1700 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 probes for the SSD-1700 are the same as those currently used in probes for other ultrasound systems currently marketed by ALOKA. These materials have been evaluated and found to be safe for this application.
- The SSD-1700 complies with the same electrical and physical safety standards as other products currently marketed by ALOKA.