

**K964549 ALOKA UST-5258-5 DIAGNOSTIC ULTRASOUND
TRANSDUCER**

Jun 3, 1997
202 days to decision

K964549 · Product code: **ITX** · Radiology
Source: <https://www.510kdatabase.net/k964549/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transducer, Ultrasonic, Diagnostic (ITX)
Date received	Nov 13, 1996
Decision date	Jun 3, 1997
Days to decision	202 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Aloka Co., Ltd.
Location	Tokyo, JP
Contact	PAUL D SMOLENSKI
510(k) history	39 submissions · 39 cleared · 1982-2011

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k964549/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 17, 2026