

K111227 ALOKA SSD-3500 DIAGNOSTIC ULTRASOUND SYSTEM

May 13, 2011
11 days to decision

K111227 · Product code: IYN · Radiology
Source: <https://www.510kdatabase.net/k111227/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	May 2, 2011
Decision date	May 13, 2011
Days to decision	11 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

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

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Device record: <https://www.510kdatabase.net/k111227/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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