

**K122341 PROSOUND F37 DIAGNOSTIC ULTRASOUND
SYSTEM, MODEL: PROSOUND F37**Sep 26, 2012
55 days to decisionK122341 · Product code: IYN · Radiology
Source: <https://www.510kdatabase.net/k122341/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Aug 2, 2012
Decision date	Sep 26, 2012
Days to decision	55 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	Hitachi Aloka Medical, Ltd.
Location	Wallingford, CT, US
510(k) history	6 submissions · 6 cleared · 2012-2015

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k122341/>; 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 16, 2026