

K061946 ACUSON X300 DIAGNOSTIC ULTRASOUND SYSTEMJul 21, 2006
11 days to decisionK061946 · Product code: IYN · Radiology
Source: <https://www.510kdatabase.net/k061946/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Jul 10, 2006
Decision date	Jul 21, 2006
Days to decision	11 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	Siemens Medical Solutions USA, Inc.
Location	Hoffman Estates, IL, US
Contact	SHEILA W PICKERING
510(k) history	778 submissions · 778 cleared · 1980-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k061946/> 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 15, 2026