

K043535 HD11 DIAGNOSTIC ULTRASOUND SYSTEMJan 6, 2005
15 days to decisionK043535 · Product code: IYN · Radiology
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Dec 22, 2004
Decision date	Jan 6, 2005
Days to decision	15 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	Philips Ultrasound, Inc.
Location	Santa Ana, CA, US
Contact	STEVE SINGLAR
510(k) history	46 submissions · 46 cleared · 1985-2021

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