

K081661 HD15 DIAGNOSTIC ULTRASOUND SYSTEMJun 24, 2008
11 days to decisionK081661 · Product code: IYN · Radiology
Source: <https://www.510kdatabase.net/k081661/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Jun 13, 2008
Decision date	Jun 24, 2008
Days to decision	11 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k081661/>, 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 26, 2026