

**K130308 NOBLUS ULTRASOUND DIAGNOSTIC SYSTEM**Apr 5, 2013  
57 days to decisionK130308 · Product code: IYN · Radiology  
Source: <https://www.510kdatabase.net/k130308/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Feb 7, 2013
Decision date	Apr 5, 2013
Days to decision	57 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Hitachi Aloka Medical, Ltd.</b>
Location	Wallingford, CT, US
Contact	ANGELA VANARSDALE
510(k) history	6 submissions · 6 cleared · 2012-2015

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k130308/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 16, 2026