

**K152250 SpeqRT**Sep 3, 2015  
24 days to decisionK152250 · Product code: **IYN** · Radiology  
Source: <https://www.510kdatabase.net/k152250/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Aug 10, 2015
Decision date	Sep 3, 2015
Days to decision	24 days
Third-party review	Yes
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Signostics Limited</b>
Location	Clovelly Park, AU
Contact	Stewart Bartlett
510(k) history	2 submissions · 2 cleared · 2015-2016

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k152250/> 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