

**K143476 Digi-One**Jun 23, 2015  
200 days to decisionK143476 · Product code: **IYN** · Radiology  
Source: <https://www.510kdatabase.net/k143476/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Dec 5, 2014
Decision date	Jun 23, 2015
Days to decision	200 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Rimed , Ltd.</b>
Location	Kfar Saba, IL
Contact	AHAVA STEIN
510(k) history	3 submissions · 3 cleared · 1998-2015

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k143476/> 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