

**K153620 Enovare Ultrasound System**May 5, 2016  
139 days to decisionK153620 · Product code: **IYO** · Radiology  
Source: <https://www.510kdatabase.net/k153620/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	Dec 18, 2015
Decision date	May 5, 2016
Days to decision	139 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Oreon Technologies, Inc.</b>
Location	Harrytown, NY, US
Contact	Howard Fidel
510(k) history	1 submissions · 1 cleared · 2016-2016

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k153620/> 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