

**K123806 FIBROSCAN**Apr 5, 2013  
116 days to decisionK123806 · Product code: **IYO** · Radiology  
Source: <https://www.510kdatabase.net/k123806/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	Dec 10, 2012
Decision date	Apr 5, 2013
Days to decision	116 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Echosens</b>
Location	Dedham, MA, US
Contact	ZVI LADIN, PH.D.
510(k) history	11 submissions · 11 cleared · 2013-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k123806/> 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 27, 2026