

K150239 FibroScanSep 1, 2015
211 days to decisionK150239 · Product code: **IYO** · Radiology
Source: <https://www.510kdatabase.net/k150239/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	Feb 2, 2015
Decision date	Sep 1, 2015
Days to decision	211 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Echosens
Location	Dedham, MA, US
Contact	Celine Fournier
510(k) history	11 submissions · 11 cleared · 2013-2023

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