

**K223902 FibroScan® device (Models: 502 Touch, 530 Compact, 430 Mini+, 230, and 630)**Mar 2, 2023  
64 days to decisionK223902 · Product code: IYO · Radiology  
Source: <https://www.510kdatabase.net/k223902/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	Dec 28, 2022
Decision date	Mar 2, 2023
Days to decision	64 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Echosens</b>
Location	Dedham, MA, US
Contact	Fanny Patoureaux
510(k) history	11 submissions · 11 cleared · 2013-2023

**REGULATORY CONSULTANT**

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Consulting firm	<b>Boston Medtech Advisors, Inc.</b>
Contact	Zvi Ladin

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k223902/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 26, 2026