

K203273 FibroScan® Family of Products (Models: 502 Touch, 530 Compact, 430 Mini+, and 630)Mar 25, 2021
139 days to decisionK203273 · Product code: IYO · Radiology
Source: <https://www.510kdatabase.net/k203273/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	Nov 6, 2020
Decision date	Mar 25, 2021
Days to decision	139 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	Boston Medtech Advisors, Inc.
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)

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