FDA 510(k) Premarket Notification

**CLEARED**

# K203273 FibroScan® Family of Products (Models: 502 Touch, 530 Compact, 430 Mini+, and 630)

Mar 25, 2021
139 days to decision

K203273 · Product code: **IYO** · Radiology
Source: https://www.510kdatabase.net/k203273/

## SUBMISSION DETAILS

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|---|---|
| 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