

K200655 FibroScan® 630Jul 16, 2020
126 days to decisionK200655 · Product code: IYO · Radiology
Source: <https://www.510kdatabase.net/k200655/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Imaging, Pulsed Echo, Ultrasonic (IYO) |
| Date received | Mar 12, 2020 |
| Decision date | Jul 16, 2020 |
| Days to decision | 126 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k200655/> Data sourced from FDA 510(k) public records (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. - Generated May 26, 2026