FDA 510(k) Premarket Notification

CLEARED

K223902 FibroScan® device (Models: 502 Touch, 530 Compact, 430 Mini+, 230, and 630)

Mar 2, 2023
64 days to decision

K223902 · Product code: **IYO** · Radiology
Source: https://www.510kdatabase.net/k223902/

SUBMISSION DETAILS

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

Company	**Echosens**
Location	Dedham, MA, US
Contact	Fanny Patoureaux
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