FDA 510(k) Premarket Notification

K212035 FibroScan 230

CLEARED

Jul 30, 2021
30 days to decision

K212035 · Product code: **IYO** · Radiology
Source: https://www.510kdatabase.net/k212035/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	Jun 30, 2021
Decision date	Jul 30, 2021
Days to decision	30 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