

K181547 FibroScan® Family of Products (Models: 502 Touch, 530 Compact, and 430 Mini+)

Jul 9, 2018
27 days to decision

K181547 · Product code: IYO · Radiology
Source: <https://www.510kdatabase.net/k181547/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	Jun 12, 2018
Decision date	Jul 9, 2018
Days to decision	27 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.net

Device record: <https://www.510kdatabase.net/k181547/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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