

K152316 iLab Ultrasound Imaging SystemSep 18, 2015
32 days to decisionK152316 · Product code: **IYO** · Radiology
Source: <https://www.510kdatabase.net/k152316/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	Aug 17, 2015
Decision date	Sep 18, 2015
Days to decision	32 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Boston Scientific
Location	San Jose, CA, US
Contact	George J Prendergast
Website	http://www.bostonscientific.com/
510(k) history	58 submissions · 52 cleared · 2001-2026

Boston Scientific is an American biotechnology and biomedical engineering firm headquartered in Marlborough, Massachusetts. The company manufactures medical devices for interventional specialties including cardiology, endoscopy, urology, and oncology. Boston Scientific has received FDA 510(k) clearances from total submissions since 2001. The company maintains active regulatory engagement, with the latest clearance in 2025. Recent cleared devices span cardiovascular, gastroenterology, urology, orthopedic, and general surgery categories, reflecting broad therapeutic focus. ...

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k152316/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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