

K153416 ArcScan Insight 100Feb 2, 2016
69 days to decisionK153416 · Product code: **IYO** · Radiology
Source: <https://www.510kdatabase.net/k153416/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	Nov 25, 2015
Decision date	Feb 2, 2016
Days to decision	69 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Arcscan, Inc.
Location	Golden, CO, US
Contact	Andy Levien
510(k) history	1 submissions · 1 cleared · 2016-2016

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k153416/> 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 16, 2026