

K150999 Acclarix Diagnostic Ultrasound SystemMay 6, 2015
21 days to decisionK150999 · Product code: **IYO** · Radiology
Source: <https://www.510kdatabase.net/k150999/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	Apr 15, 2015
Decision date	May 6, 2015
Days to decision	21 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	Edan Instruments, Inc.
Location	Shenzhen, CN
Contact	QUEENA CHEN
Website	https://www.edan.com.cn
510(k) history	92 submissions · 92 cleared · 2004-2026

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