

K161300 Acclarix AX8 Diagnostic Ultrasound SystemMay 31, 2016
22 days to decisionK161300 · Product code: IYO · Radiology
Source: <https://www.510kdatabase.net/k161300/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	May 9, 2016
Decision date	May 31, 2016
Days to decision	22 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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