

K171900 Acclarix AX4 Diagnostic Ultrasound SystemAug 18, 2017
53 days to decisionK171900 · Product code: **IYN** · Radiology
Source: <https://www.510kdatabase.net/k171900/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Jun 26, 2017
Decision date	Aug 18, 2017
Days to decision	53 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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