

K123249 DIAGNOSTIC ULTRASOUND SYSTEMFeb 8, 2013
114 days to decisionK123249 · Product code: **IYN** · Radiology
Source: <https://www.510kdatabase.net/k123249/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Oct 17, 2012
Decision date	Feb 8, 2013
Days to decision	114 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

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

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