

K173003 U50 Diagnostic Ultrasound SystemNov 15, 2017
49 days to decisionK173003 · Product code: **IYN** · Radiology
Source: <https://www.510kdatabase.net/k173003/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Sep 27, 2017
Decision date	Nov 15, 2017
Days to decision	49 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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