

K180408 U60 Diagnostic Ultrasound SystemApr 13, 2018
58 days to decisionK180408 · Product code: **IYN** · Radiology
Source: <https://www.510kdatabase.net/k180408/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Feb 14, 2018
Decision date	Apr 13, 2018
Days to decision	58 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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