

K172380 U2 Diagnostic Ultrasound SystemSep 29, 2017
53 days to decisionK172380 · Product code: **IYN** · Radiology
Source: <https://www.510kdatabase.net/k172380/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Aug 7, 2017
Decision date	Sep 29, 2017
Days to decision	53 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k172380/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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