

K180862 Acclarix LX8 Diagnostic Ultrasound System, Acclarix AX8 Diagnostic Ultrasound SystemMay 24, 2018
52 days to decisionK180862 · Product code: IYN · Radiology
Source: <https://www.510kdatabase.net/k180862/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Apr 2, 2018
Decision date	May 24, 2018
Days to decision	52 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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