

K162055 Acclarix LX8 Diagnostic Ultrasound SystemJan 31, 2017
190 days to decisionK162055 · Product code: **IYN** · Radiology
Source: <https://www.510kdatabase.net/k162055/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Jul 25, 2016
Decision date	Jan 31, 2017
Days to decision	190 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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