

K192879 Acclarix AX8 Diagnostic Ultrasound System / Acclarix LX9 Series Diagnostic Ultrasound SystemMay 21, 2020
234 days to decisionK192879 · Product code: IYN · Radiology
Source: <https://www.510kdatabase.net/k192879/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Sep 30, 2019
Decision date	May 21, 2020
Days to decision	234 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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