

K190186 Acclarix AX4 Diagnostic Ultrasound System / Acclarix LX4 Diagnostic Ultrasound SystemMar 28, 2019
55 days to decisionK190186 · Product code: IYO · Radiology
Source: <https://www.510kdatabase.net/k190186/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	Feb 1, 2019
Decision date	Mar 28, 2019
Days to decision	55 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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