FDA 510(k) Premarket Notification

CLEARED

Feb 20, 2025
27 days to decision

K250214 Acclarix AX8 Series Diagnostic Ultrasound System (Model: Acclarix AX7, Acclarix AX8, Acclarix AX75, Acclarix AX78, Acclarix AX8 Exp, Acclarix AX8 Super), Acclarix AX9 Series Diagnostic Ultrasound Szystem (Model: Acclarix AX9 Basic, Acclarix AX9, Acclarix AX9 Exp, Acclarix AX9 Super, Acclarix AX85, Acclarix AX88)

K250214 · Product code: **IYN** · Radiology
Source: https://www.510kdatabase.net/k250214/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Jan 24, 2025
Decision date	Feb 20, 2025
Days to decision	27 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	**Regulatory Technology Services, LLC**
Contact	Prithul Bom

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov