CLEARED

Jan 25, 2021
119 days to decision

K202856 Diagnostic Ultrasound System, Models: Acclarix AX3, Acclarix AX3 Exp, Acclarix AX3 Super, Acclarix AX25, Acclarix AX28, Acclarix AX2, Acclarix AX2 Exp, Acclarix AX2 Super, Acclarix AX15, Acclarix AX18, Acclarix LX3, Acclarix LX3 Exp, Acclarix LX3 Super, Acclarix LX25 and Acclarix LX28

K202856 · Product code: **IYN** · Radiology
Source: https://www.510kdatabase.net/k202856/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Sep 28, 2020
Decision date	Jan 25, 2021
Days to decision	119 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k202856/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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