FDA 510(k) Premarket Notification

K252463 SE-1202 Series Electrocardiograph (Model: SE-1202, SE-1202E)

CLEARED

Jul 2, 2026
330 days to decision

K252463 · Product code: **DPS** · Cardiovascular
Source: https://www.510kdatabase.net/k252463/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrocardiograph (DPS)
Date received	Aug 6, 2025
Decision date	Jul 2, 2026
Days to decision	330 days
Third-party review	No
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	93 submissions · 93 cleared · 2004-2026