

K212278 ElectrocardiographApr 7, 2022
261 days to decisionK212278 · Product code: **DPS** · Cardiovascular
Source: <https://www.510kdatabase.net/k212278/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrocardiograph (DPS)
Date received	Jul 20, 2021
Decision date	Apr 7, 2022
Days to decision	261 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

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