

K210140 electrocardiograph: SE-1202Oct 1, 2021
255 days to decisionK210140 · Product code: **DPS** · Cardiovascular
Source: <https://www.510kdatabase.net/k210140/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrocardiograph (DPS)
Date received	Jan 19, 2021
Decision date	Oct 1, 2021
Days to decision	255 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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