

K120188 ELECTROCARDIOGRAPHMar 16, 2012
53 days to decisionK120188 · Product code: **DPS** · CardiovascularSource: <https://www.510kdatabase.net/k120188/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Electrocardiograph (DPS)
Date received	Jan 23, 2012
Decision date	Mar 16, 2012
Days to decision	53 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k120188/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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