

K161302 PC ECGJul 1, 2016
53 days to decisionK161302 · Product code: **DPS** · CardiovascularSource: <https://www.510kdatabase.net/k161302/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrocardiograph (DPS)
Date received	May 9, 2016
Decision date	Jul 1, 2016
Days to decision	53 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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