

**K102854 PC ECG**Dec 3, 2010  
65 days to decisionK102854 · Product code: **DPS** · CardiovascularSource: <https://www.510kdatabase.net/k102854/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Electrocardiograph (DPS)
Date received	Sep 29, 2010
Decision date	Dec 3, 2010
Days to decision	65 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k102854/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 20, 2026