

**K091513 SMART ECG SERIES ELECTROCARDIOGRAPH,  
MODELS SE-3, SE-300A AND 300B, SE-6, SE-600, SE-12, SE-12  
EXPRESS AND SE-1200**Jul 24, 2009  
63 days to decisionK091513 · Product code: **DPS** · Cardiovascular  
Source: <https://www.510kdatabase.net/k091513/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrocardiograph (DPS)
Date received	May 22, 2009
Decision date	Jul 24, 2009
Days to decision	63 days
Third-party review	Yes
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Edan Instruments, Inc.</b>
Location	Shenzhen, CN
Contact	WILLIAM STERN
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/k091513/> 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 22, 2026