

**K093869 SE-601 SERIES ELECTROCARDIOGRAPH**Apr 1, 2010  
105 days to decisionK093869 · Product code: **DPS** · CardiovascularSource: <https://www.510kdatabase.net/k093869/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrocardiograph (DPS)
Date received	Dec 17, 2009
Decision date	Apr 1, 2010
Days to decision	105 days
Third-party review	No
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/k093869/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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