

K092010 PC ECG, MODEL SE-1010Oct 22, 2009
108 days to decisionK092010 · Product code: **DPS** · CardiovascularSource: <https://www.510kdatabase.net/k092010/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrocardiograph (DPS)
Date received	Jul 6, 2009
Decision date	Oct 22, 2009
Days to decision	108 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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