

**K863116 CARDIOFAX ECG-6551 (ELECTROCARDIOGRPH)**Sep 17, 1986  
34 days to decisionK863116 · Product code: **DPS** · Cardiovascular  
Source: <https://www.510kdatabase.net/k863116/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrocardiograph (DPS)
Date received	Aug 14, 1986
Decision date	Sep 17, 1986
Days to decision	34 days
Third-party review	No

**APPLICANT**

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Company	<b>Nihon Kohden America, Inc.</b>
Location	Foothill Ranch, CA, US
Contact	JANICE SEBENS
510(k) history	166 submissions · 163 cleared · 1979-2012

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k863116/>; 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 May 24, 2026