

**K990031 NIHON KOHDEN ECG-9010K AND ECG-9020K  
CARDIOFAX GEM AND ACCESSORIES**Apr 16, 1999  
101 days to decisionK990031 · Product code: **LOS** · Cardiovascular  
Source: <https://www.510kdatabase.net/k990031/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Date received	Jan 5, 1999
Decision date	Apr 16, 1999
Days to decision	101 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Nihon Kohden America, Inc.</b>
Location	Foothill Ranch, CA, US
Contact	GARY REASONER
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/k990031/> 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