

**K865031 ELECTROCARDIOGRAPH**Feb 19, 1987  
58 days to decisionK865031 · Product code: **DPS** · CardiovascularSource: <https://www.510kdatabase.net/k865031/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrocardiograph (DPS)
Date received	Dec 23, 1986
Decision date	Feb 19, 1987
Days to decision	58 days
Third-party review	No

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k865031/>, 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