

K860212 CARDIOFAX ECG-6353Apr 17, 1986
85 days to decisionK860212 · Product code: **DPS** · Cardiovascular
Source: <https://www.510kdatabase.net/k860212/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrocardiograph (DPS)
Date received	Jan 22, 1986
Decision date	Apr 17, 1986
Days to decision	85 days
Third-party review	No

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k860212/>; Data sourced from FDA 510(k) public records (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. - Generated May 24, 2026