

K922394 CARDIOFAX Q ECG-8420AMar 1, 1994
650 days to decisionK922394 · Product code: **LOS** · CardiovascularSource: <https://www.510kdatabase.net/k922394/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Date received	May 20, 1992
Decision date	Mar 1, 1994
Days to decision	650 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k922394/>; 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