

**K891462 ROCHE(R) CARDIOSCREEN-CK**May 22, 1989  
68 days to decisionK891462 · Product code: **CGS** · Chemistry  
Source: <https://www.510kdatabase.net/k891462/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nad Reduction/nadh Oxidation, Cpk Or Isoenzymes (CGS)
Date received	Mar 15, 1989
Decision date	May 22, 1989
Days to decision	68 days
Third-party review	No
Combination product	No
PCCP authorized	No

**APPLICANT**

---

Company	<b>Roche Diagnostic Systems, Inc.</b>
Location	Mchenry, IL, US
Contact	ALEX WESOLOWSKI
510(k) history	296 submissions · 296 cleared · 1983-1999

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k891462/> 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 June 23, 2026