

K850212 ISOENZYME TEST CK-MBFeb 7, 1985
23 days to decisionK850212 · Product code: **CGS** · Chemistry
Source: <https://www.510kdatabase.net/k850212/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nad Reduction/nadh Oxidation, Cpk Or Isoenzymes (CGS)
Date received	Jan 15, 1985
Decision date	Feb 7, 1985
Days to decision	23 days
Third-party review	No

APPLICANT

Company	Sclavo, Inc.
Location	Mchenry, IL, US
Contact	DEBRA HOFMEISTER
510(k) history	82 submissions · 82 cleared · 1977-1992

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k850212/>; 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 June 29, 2026