

K860669 CREATINE KINASE, N-ACETYL-L-CYSTIENEApr 7, 1986
42 days to decisionK860669 · Product code: **CGS** · Chemistry
Source: <https://www.510kdatabase.net/k860669/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nad Reduction/nadh Oxidation, Cpk Or Isoenzymes (CGS)
Date received	Feb 24, 1986
Decision date	Apr 7, 1986
Days to decision	42 days
Third-party review	No

APPLICANT

Company	Em Diagnostic Systems, Inc.
Location	Walker, MI, US
Contact	RAYMOND L MILLER
510(k) history	288 submissions · 288 cleared · 1984-1994

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k860669/>; 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 14, 2026