

**K852483 SYSTEMATE CK-MB(NAC-ACTIVATED) ITEM NO.
67205**Jul 12, 1985
31 days to decisionK852483 · Product code: **CGS** · Chemistry
Source: <https://www.510kdatabase.net/k852483/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nad Reduction/nadh Oxidation, Cpk Or Isoenzymes (CGS)
Date received	Jun 11, 1985
Decision date	Jul 12, 1985
Days to decision	31 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/k852483/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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