

**K861061 EMDS CREATINE KINASE ISOENZYME CKMB TEST
PACK**Apr 24, 1986
35 days to decisionK861061 · Product code: **CGS** · Chemistry
Source: <https://www.510kdatabase.net/k861061/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nad Reduction/nadh Oxidation, Cpk Or Isoenzymes (CGS)
Date received	Mar 20, 1986
Decision date	Apr 24, 1986
Days to decision	35 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/k861061/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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