

K914361 CREATINE KINASE MB TEST ITEM NUMBER 5A46Dec 13, 1991
73 days to decisionK914361 · Product code: **CGS** · Chemistry
Source: <https://www.510kdatabase.net/k914361/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nad Reduction/nadh Oxidation, Cpk Or Isoenzymes (CGS)
Date received	Oct 1, 1991
Decision date	Dec 13, 1991
Days to decision	73 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

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