

K854501 CK(OPTIMIZED) REAGENTDec 4, 1985
22 days to decisionK854501 · Product code: **CGS** · Chemistry
Source: <https://www.510kdatabase.net/k854501/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nad Reduction/nadh Oxidation, Cpk Or Isoenzymes (CGS)
Date received	Nov 12, 1985
Decision date	Dec 4, 1985
Days to decision	22 days
Third-party review	No

APPLICANT

Company	Sigma Diagnostics, Inc.
Location	Mchenry, IL, US
Contact	MATHEW MADAPPALLY
510(k) history	164 submissions · 164 cleared · 1984-2002

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