

**K935463 CREATINE KINASE-MB (CK-MB) REAGENT SET**Jan 11, 1994  
60 days to decisionK935463 · Product code: **CGS** · Chemistry  
Source: <https://www.510kdatabase.net/k935463/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nad Reduction/nadh Oxidation, Cpk Or Isoenzymes (CGS)
Date received	Nov 12, 1993
Decision date	Jan 11, 1994
Days to decision	60 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Pointe Scientific, Inc.,</b>
Location	Mchenry, IL, US
Contact	WILLIAM F WALTERS
510(k) history	74 submissions · 74 cleared · 1981-2007

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