

**K903025 ROCHE ISOMUNE- CK**Aug 9, 1990  
30 days to decisionK903025 · Product code: **JHS** · Chemistry  
Source: <https://www.510kdatabase.net/k903025/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Differential Rate Kinetic Method, Cpk Or Isoenzymes (JHS)
Date received	Jul 10, 1990
Decision date	Aug 9, 1990
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No

**APPLICANT**

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Company	<b>Roche Diagnostic Systems, Inc.</b>
Location	Mchenry, IL, US
Contact	ALEX WESOLOWSKI
510(k) history	296 submissions · 296 cleared · 1983-1999

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