

K896240 COBAS READY CK REAGENTFeb 16, 1990
109 days to decisionK896240 · Product code: **JHY** · Chemistry
Source: <https://www.510kdatabase.net/k896240/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Colorimetric Method, Cpk Or Isoenzymes (JHY)
Date received	Oct 30, 1989
Decision date	Feb 16, 1990
Days to decision	109 days
Third-party review	No
Combination product	No
PCCP authorized	No

APPLICANT

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

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