

K896237 COBAS READY ALT REAGENTFeb 16, 1990
108 days to decisionK896237 · Product code: **CKD** · Chemistry
Source: <https://www.510kdatabase.net/k896237/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hydrazone Colorimetry, Alt/sgpt (CKD)
Date received	Oct 31, 1989
Decision date	Feb 16, 1990
Days to decision	108 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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Device record: <https://www.510kdatabase.net/k896237/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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