

K883453 ROCHE REAGENT FOR CALCIUMOct 25, 1988
74 days to decisionK883453 · Product code: **CJY** · Chemistry
Source: <https://www.510kdatabase.net/k883453/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Azo Dye, Calcium (CJY)
Date received	Aug 12, 1988
Decision date	Oct 25, 1988
Days to decision	74 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/k883453/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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