

K801295 COBAS REAGENT FOR A-AMYLASEJul 8, 1980
36 days to decisionK801295 · Product code: **JFJ** · Chemistry
Source: <https://www.510kdatabase.net/k801295/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catalytic Methods, Amylase (JFJ)
Date received	Jun 2, 1980
Decision date	Jul 8, 1980
Days to decision	36 days
Third-party review	No

APPLICANT

Company	Roche Analytical Instruments, Inc.
Location	Mchenry, IL, US
510(k) history	11 submissions · 11 cleared · 1980-1980

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Device record: <https://www.510kdatabase.net/k801295/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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