

K935362 P-AMYLASE CONTROLJan 27, 1994
84 days to decisionK935362 · Product code: **JJX** · Chemistry
Source: <https://www.510kdatabase.net/k935362/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Single (specified) Analyte Controls (assayed And Unassayed) (JJX)
Date received	Nov 4, 1993
Decision date	Jan 27, 1994
Days to decision	84 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Beckman
Location	Brea, CA, US
Contact	DON W HART
Website	http://www.beckmancoulter.com/
510(k) history	6 submissions · 6 cleared · 1989-1999

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Device record: <https://www.510kdatabase.net/k935362/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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