

K903309 ROCHE COBAS READY AMYLASE REAGENTSep 7, 1990
45 days to decisionK903309 · Product code: **JFJ** · Chemistry
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catalytic Methods, Amylase (JFJ)
Date received	Jul 24, 1990
Decision date	Sep 7, 1990
Days to decision	45 days
Third-party review	No
Combination product	No
PCCP authorized	No

APPLICANT

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

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