

**K972250 ROCHE COBAS INTEGRA REAGENT CASSETTES &
ANCILLARY REAGENTS**Aug 12, 1997
57 days to decisionK972250 · Product code: JFJ · Chemistry
Source: <https://www.510kdatabase.net/k972250/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catalytic Methods, Amylase (JFJ)
Date received	Jun 16, 1997
Decision date	Aug 12, 1997
Days to decision	57 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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