

K964457 ROCHE COBAS IBTEGRA REAGENT CASSETTESJan 13, 1997
68 days to decisionK964457 · Product code: **JQB** · Chemistry
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Kinetic Method, Gamma-glutamyl Transpeptidase (JQB)
Date received	Nov 6, 1996
Decision date	Jan 13, 1997
Days to decision	68 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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