

**K972214 ROCHE SERUM CONTROL NORMAL (HUMAN),
ROCHE SERUM CONTROL PATHOLOGICAL (HUMAN)**Jun 24, 1997
12 days to decisionK972214 · Product code: JJY · Chemistry
Source: <https://www.510kdatabase.net/k972214/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Multi-analyte Controls, All Kinds (assayed) (JJY)
Date received	Jun 12, 1997
Decision date	Jun 24, 1997
Days to decision	12 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

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