

K972721 ROCHE HEMOGLOBIN A1C CONTROL N AND CONTROL PAug 6, 1997
16 days to decisionK972721 · Product code: **JJX** · Chemistry
Source: <https://www.510kdatabase.net/k972721/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Single (specified) Analyte Controls (assayed And Unassayed) (JJX)
Date received	Jul 21, 1997
Decision date	Aug 6, 1997
Days to decision	16 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k972721/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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