

K942048 ROCHE AMMONIA (VARIOUS)Oct 4, 1994
159 days to decisionK942048 · Product code: **DKB** · Chemistry
Source: <https://www.510kdatabase.net/k942048/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calibrators, Drug Mixture (DKB)
Date received	Apr 28, 1994
Decision date	Oct 4, 1994
Days to decision	159 days
Third-party review	No
Summary / Statement	Statement

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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