

K954000 ROCHE REAGENT FOR BUNOct 25, 1995
61 days to decisionK954000 · Product code: **CDQ** · Chemistry
Source: <https://www.510kdatabase.net/k954000/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Urease And Glutamic Dehydrogenase, Urea Nitrogen (CDQ)
Date received	Aug 25, 1995
Decision date	Oct 25, 1995
Days to decision	61 days
Third-party review	No
Summary / Statement	Statement

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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