

K801116 COBAS REAGENT FOR BUNJun 17, 1980
36 days to decisionK801116 · Product code: **CDQ** · Chemistry
Source: <https://www.510kdatabase.net/k801116/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Urease And Glutamic Dehydrogenase, Urea Nitrogen (CDQ)
Date received	May 12, 1980
Decision date	Jun 17, 1980
Days to decision	36 days
Third-party review	No

APPLICANT

Company	Roche Analytical Instruments, Inc.
Location	Mchenry, IL, US
510(k) history	11 submissions · 11 cleared · 1980-1980

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Device record: <https://www.510kdatabase.net/k801116/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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