

K801117 COBAS TOTAL BILIRUBIN REAGENT & DILUENTJun 9, 1980
28 days to decisionK801117 · Product code: **CIG** · Chemistry
Source: <https://www.510kdatabase.net/k801117/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Diazo Colorimetry, Bilirubin (CIG)
Date received	May 12, 1980
Decision date	Jun 9, 1980
Days to decision	28 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/k801117/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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