

**K801297 COBAS REAGENT FOR GLUCOSE RAPID**Jun 30, 1980  
28 days to decisionK801297 · Product code: **CFR** · Chemistry  
Source: <https://www.510kdatabase.net/k801297/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hexokinase, Glucose (CFR)
Date received	Jun 2, 1980
Decision date	Jun 30, 1980
Days to decision	28 days
Third-party review	No

**APPLICANT**

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

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Device record: <https://www.510kdatabase.net/k801297/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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