

**K003261 CREATININE PLUS**Nov 16, 2000  
29 days to decisionK003261 · Product code: **JFY** · Chemistry  
Source: <https://www.510kdatabase.net/k003261/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Enzymatic Method, Creatinine (JFY)
Date received	Oct 18, 2000
Decision date	Nov 16, 2000
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Roche Diagnostics Corp.</b>
Location	Indianapolis, IN, US
Contact	PRISCILLA A HAMILL
510(k) history	264 submissions · 263 cleared · 1999-2013

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