

**K984626 ARCHITECT B12 MASTERCHEK, MODEL # 6C09-O5**Jan 29, 1999  
32 days to decisionK984626 · Product code: **JJX** · Chemistry  
Source: <https://www.510kdatabase.net/k984626/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Single (specified) Analyte Controls (assayed And Unassayed) (JJX)
Date received	Dec 28, 1998
Decision date	Jan 29, 1999
Days to decision	32 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Bio-Rad</b>
Location	Mchenry, IL, US
Contact	ELIZABETH PLATT
Website	<a href="http://www.bio-rad.com">http://www.bio-rad.com</a>
510(k) history	319 submissions · 319 cleared · 1976-2017

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k984626/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 14, 2026