

**K003095 FASTPACK CONTROL**Nov 29, 2000  
57 days to decisionK003095 · Product code: **JJX** · Immunology  
Source: <https://www.510kdatabase.net/k003095/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Single (specified) Analyte Controls (assayed And Unassayed) (JJX)
Date received	Oct 3, 2000
Decision date	Nov 29, 2000
Days to decision	57 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Qualigen, Inc.</b>
Location	Carlsbad, CA, US
Contact	DOROTHY DEINZER
510(k) history	15 submissions · 15 cleared · 2000-2019

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k003095/> 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 June 19, 2026