

K003096 FASTPACK CALIBRATORSNov 30, 2000
58 days to decisionK003096 · Product code: **JIT** · Immunology
Source: <https://www.510kdatabase.net/k003096/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Calibrator, Secondary (JIT)
Date received	Oct 3, 2000
Decision date	Nov 30, 2000
Days to decision	58 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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