

K062957 FASTPACK TOTAL PSA METHOD VERIFICATION KITApr 2, 2007
185 days to decisionK062957 · Product code: **JJX** · Immunology
Source: <https://www.510kdatabase.net/k062957/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Single (specified) Analyte Controls (assayed And Unassayed) (JJX)
Date received	Sep 29, 2006
Decision date	Apr 2, 2007
Days to decision	185 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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