

K123725 FASTPACK CONTROL KITMar 8, 2013
94 days to decisionK123725 · Product code: **JJY** · Chemistry
Source: <https://www.510kdatabase.net/k123725/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Multi-analyte Controls, All Kinds (assayed) (JJY)
Date received	Dec 4, 2012
Decision date	Mar 8, 2013
Days to decision	94 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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