

K123983 FASTPACK VITAMIN DJul 3, 2013
189 days to decisionK123983 · Product code: **MRG** · Chemistry
Source: <https://www.510kdatabase.net/k123983/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Vitamin D (MRG)
Date received	Dec 26, 2012
Decision date	Jul 3, 2013
Days to decision	189 days
Third-party review	No
Summary / Statement	Summary
Other names	IMMUNOASSAY, CALIBRATORS, CONTROLS, VERIFIERS

APPLICANT

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

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