

K101388 FASTPACK TESTO IMMUNOASSAYFeb 18, 2011
277 days to decisionK101388 · Product code: **CDZ** · Chemistry
Source: <https://www.510kdatabase.net/k101388/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Radioimmunoassay, Testosterones And Dihydrotestosterone (CDZ)
Date received	May 17, 2010
Decision date	Feb 18, 2011
Days to decision	277 days
Third-party review	No
Summary / Statement	Summary

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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