

**K182521 FastPack IP Sex Hormone Binding Globulin
Immunoassay**Jan 29, 2019
138 days to decisionK182521 · Product code: **CDZ** · Chemistry
Source: <https://www.510kdatabase.net/k182521/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Testosterones And Dihydrotestosterone (CDZ)
Date received	Sep 13, 2018
Decision date	Jan 29, 2019
Days to decision	138 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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