

**K021972 FASTPACK TOTAL TESTOSTERONE IMMUNOASSAY**Aug 21, 2002  
65 days to decisionK021972 · Product code: **CDZ** · Chemistry  
Source: <https://www.510kdatabase.net/k021972/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Testosterones And Dihydrotestosterone (CDZ)
Date received	Jun 17, 2002
Decision date	Aug 21, 2002
Days to decision	65 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Qualigen, Inc.</b>
Location	Carlsbad, CA, US
Contact	DOROTHY DEINZER
510(k) history	15 submissions · 15 cleared · 2000-2019

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k021972/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 19, 2026