

**K003094 FASTPACK PSA IMMUNOASSAY, FASTPACK ANALYZER**

Oct 25, 2000  
22 days to decision

K003094 · Product code: **LTJ** · Immunology  
Source: <https://www.510kdatabase.net/k003094/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Prostate-specific Antigen (psa) For Management Of Prostate Cancers (LTJ)
Date received	Oct 3, 2000
Decision date	Oct 25, 2000
Days to decision	22 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/k003094/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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