

K994419 FASTPACK PSA IMMUNOASSAY, FASTPACK SYSTEMJun 28, 2000
182 days to decisionK994419 · Product code: **LTJ** · Immunology
Source: <https://www.510kdatabase.net/k994419/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prostate-specific Antigen (psa) For Management Of Prostate Cancers (LTJ)
Date received	Dec 29, 1999
Decision date	Jun 28, 2000
Days to decision	182 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Qualisys Diagnostics, Inc.
Location	Irvine, CA, US
Contact	VIJAY K MAHANT
510(k) history	2 submissions · 2 cleared · 1999-2000

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