

K964595 OPUS PSA TEST SYSTEMJun 24, 1997
218 days to decisionK964595 · Product code: **LTJ** · Immunology
Source: <https://www.510kdatabase.net/k964595/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prostate-specific Antigen (psa) For Management Of Prostate Cancers (LTJ)
Date received	Nov 18, 1996
Decision date	Jun 24, 1997
Days to decision	218 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Behring Diagnostics, Inc.
Location	Mchenry, IL, US
Contact	KATHLEEN DRAY-LYONS
510(k) history	145 submissions · 145 cleared · 1976-1997

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