

K964351 ELECSYS PSA ASSAYJul 25, 1997
266 days to decisionK964351 · Product code: **LTJ** · Immunology
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prostate-specific Antigen (psa) For Management Of Prostate Cancers (LTJ)
Date received	Nov 1, 1996
Decision date	Jul 25, 1997
Days to decision	266 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Boehringer Mannheim Corp.
Location	Mchenry, IL, US
Contact	MARY KONING
510(k) history	340 submissions · 340 cleared · 1976-1999

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