

K965085 ENZYMUN-TEST PSAMar 19, 1997
90 days to decisionK965085 · 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	Dec 19, 1996
Decision date	Mar 19, 1997
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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