

K974189 ELECSYS PSA (ON ELECSYS 1010)Jan 6, 1998
60 days to decisionK974189 · 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 7, 1997
Decision date	Jan 6, 1998
Days to decision	60 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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