

K994221 BAYER PSA ASSAYApr 13, 2000
120 days to decisionK994221 · Product code: **LTJ** · Immunology
Source: <https://www.510kdatabase.net/k994221/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prostate-specific Antigen (psa) For Management Of Prostate Cancers (LTJ)
Date received	Dec 15, 1999
Decision date	Apr 13, 2000
Days to decision	120 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Bayer Corp.
Location	Elkhart, IN, US
Contact	William J Pignato
510(k) history	96 submissions · 96 cleared · 1989-2003

Bayer Corp. is the American subsidiary of Bayer AG, headquartered in Whippany, New Jersey. The company operates 40 fully consolidated subsidiaries across 19 states. Bayer Corp. received FDA 510(k) clearances from total submissions, with no denied submissions on record. The company's regulatory activity spans from 1989 to 2003, with a primary focus on chemistry devices and immunology assays. Notable cleared devices include the ASCENSIA BREEZE BLOOD GLUCOSE METER, CLINITEST PREGNANCY TEST, and the ADVIA CENTAUR immunoassay system. This represents a historical regulatory rec...