

**K022177 PROSTATE SPECIFIC ANTIGEN (PSA) ASSAY FOR
THE ADVIA INTEGRATED MODULAR SYSTEM**Dec 17, 2002
167 days to decisionK022177 · Product code: **LTJ** · Immunology
Source: <https://www.510kdatabase.net/k022177/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prostate-specific Antigen (psa) For Management Of Prostate Cancers (LTJ)
Date received	Jul 3, 2002
Decision date	Dec 17, 2002
Days to decision	167 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Bayer Diagnostics Corp.
Location	Medfield, MA, US
Contact	KENNETH T EDDES
510(k) history	32 submissions · 32 cleared · 2000-2003

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k022177/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 28, 2026