CLEARED

K022288 COMPLEXED PROSTATE SPECIFIC ANTIGEN (CPSA) ASSAY FOR THE BAYER ADVIA INTEGRATED MODULE SYSTEM

Dec 17, 2002
155 days to decision

K022288 · Product code: **LTJ** · Immunology
Source: https://www.510kdatabase.net/k022288/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prostate-specific Antigen (psa) For Management Of Prostate Cancers (LTJ)
Date received	Jul 15, 2002
Decision date	Dec 17, 2002
Days to decision	155 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Bayer Corp.**
Location	Elkhart, IN, US
Contact	KENNETH T EDDS
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...