

**K983715 THE IMMUNO 1 CA 125 II ASSAY FOR THE BAYER
IMMUNO 1 SYSTEM (IN VITRO DIAGNOSTIC SYSTEM)**May 14, 1999
205 days to decisionK983715 · Product code: LTK · Immunology
Source: <https://www.510kdatabase.net/k983715/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Epithelial Ovarian Tumor-associated Antigen (ca125) (LTK)
Date received	Oct 21, 1998
Decision date	May 14, 1999
Days to decision	205 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Bayer Corp.
Location	Elkhart, IN, US
Contact	GABRIEL J MURACA, JR.
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...

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Device record: <https://www.510kdatabase.net/k983715/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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