

**K983345 BAYER IMMUNO 1 SYSTEM, UPGRADED FOR A LABORATORY**Dec 7, 1998  
75 days to decisionK983345 · Product code: **JJE** · Chemistry  
Source: <https://www.510kdatabase.net/k983345/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Analyzer, Chemistry (photometric, Discrete), For Clinical Use (JJE)
Date received	Sep 23, 1998
Decision date	Dec 7, 1998
Days to decision	75 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Bayer Corp.</b>
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...