

**K024234 ASCENSIA GLUCOFACTS**Jan 23, 2003  
31 days to decisionK024234 · Product code: **NBW** · Chemistry  
Source: <https://www.510kdatabase.net/k024234/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Blood Glucose, Over The Counter (NBW)
Date received	Dec 23, 2002
Decision date	Jan 23, 2003
Days to decision	31 days
Third-party review	No
Summary / Statement	Summary
Other names	ASCENSIA GLUCOFACTS PROFESSIONAL

**APPLICANT**

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Company	<b>Bayer Corp.</b>
Location	Elkhart, IN, US
Contact	GEORGE M TANCOS
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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