

K023584 ASCENSIA DEX 2 DIABETES CARE SYSTEMNov 20, 2002
26 days to decisionK023584 · Product code: **NBW** · Chemistry
Source: <https://www.510kdatabase.net/k023584/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Test, Blood Glucose, Over The Counter (NBW)
Date received	Oct 25, 2002
Decision date	Nov 20, 2002
Days to decision	26 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Bayer Corp.
Location	Elkhart, IN, US
Contact	GEORGE M TANCROS
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...
