

K971209 CLINITEK HCG TEST STRIPSApr 4, 1997
2 days to decisionK971209 · Product code: **JHI** · Chemistry
Source: <https://www.510kdatabase.net/k971209/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Visual, Pregnancy Hcg, Prescription Use (JHI)
Date received	Apr 2, 1997
Decision date	Apr 4, 1997
Days to decision	2 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	Bayer Corp.
Location	Elkhart, IN, US
Contact	ROSEANNE SAVOL
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, CLINITEK PREGNANCY TEST, and the ADVIA CENTAUR immunoassay system. This represents a historical regulatory rec...