

**K981312 3RD GENERATION TSH ASSAY FOR THE BAYER
IMMUNO 1 SYSTEM**Jun 5, 1998
56 days to decisionK981312 · Product code: **JLW** · Chemistry
Source: <https://www.510kdatabase.net/k981312/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Thyroid-stimulating Hormone (JLW)
Date received	Apr 10, 1998
Decision date	Jun 5, 1998
Days to decision	56 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...