

**K952075 PROGESTERONE ASSAY FOR THE TECHNICON  
IMMUNO 1 SYSTEM IN-BITRO DIAGNOSTIC SYSTEM**Jun 13, 1995  
41 days to decisionK952075 · Product code: **JLS** · Chemistry  
Source: <https://www.510kdatabase.net/k952075/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Progesterone (JLS)
Date received	May 3, 1995
Decision date	Jun 13, 1995
Days to decision	41 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...