

**K020217 ACS:180 AND ADVIA CENTAUR IPTH IMMUNOASSAY**Mar 15, 2002  
52 days to decisionK020217 · Product code: **JJX** · Chemistry  
Source: <https://www.510kdatabase.net/k020217/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Single (specified) Analyte Controls (assayed And Unassayed) (JJX)
Date received	Jan 22, 2002
Decision date	Mar 15, 2002
Days to decision	52 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Bayer Diagnostics Corp.</b>
Location	Medfield, MA, US
Contact	KENNETH T EDDES
510(k) history	32 submissions · 32 cleared · 2000-2003

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k020217/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 28, 2026