

**K013492 IMUBIND TPA ELISA, MODEL 860**Mar 13, 2002  
142 days to decisionK013492 · Product code: **GGP** · Hematology  
Source: <https://www.510kdatabase.net/k013492/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Qualitative And Quantitative Factor Deficiency (GGP)
Date received	Oct 22, 2001
Decision date	Mar 13, 2002
Days to decision	142 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>American Diagnostica, Inc.</b>
Location	Greenwich, CT, US
Contact	JOHN B BERRYMAN
510(k) history	10 submissions · 10 cleared · 1994-2008

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k013492/> 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 25, 2026