

**K952251 IMMULITE HCG HIGH LEVEL CONTROL MODULE**Sep 8, 1995  
116 days to decisionK952251 · Product code: **JJX** · Chemistry  
Source: <https://www.510kdatabase.net/k952251/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Single (specified) Analyte Controls (assayed And Unassayed) (JJX)
Date received	May 15, 1995
Decision date	Sep 8, 1995
Days to decision	116 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Diagnostic Products Corp.</b>
Location	Mchenry, IL, US
Contact	KENNETH B ASARCH
510(k) history	321 submissions · 321 cleared · 1976-2006

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k952251/> 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 20, 2026