

**K851541 DART IMMUNOGLOBULINS REAGENT SYSTEM**Jul 15, 1985  
90 days to decisionK851541 · Product code: **DEW** · Immunology  
Source: <https://www.510kdatabase.net/k851541/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Igg, Antigen, Antiserum, Control (DEW)
Date received	Apr 16, 1985
Decision date	Jul 15, 1985
Days to decision	90 days
Third-party review	No

**APPLICANT**

---

Company	<b>Coulter Electronics, Inc.</b>
Location	Mchenry, IL, US
Contact	RICHARDSON-JONES
510(k) history	101 submissions · 101 cleared · 1976-1994

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k851541/>, 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 May 14, 2026