

**K061069 SPIFE IFE-15 PENTAVALENT, MODEL 3456, SPIFE IFE-9 PENTAVALENT KIT, MODEL 3457, SPIFT IFE-6 PENTAVALENT KIT, MODEL 3458**Jul 6, 2006  
80 days to decisionK061069 · Product code: **CFF** · Immunology  
Source: <https://www.510kdatabase.net/k061069/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Immunoelectrophoretic, Immunoglobulins, (g, A, M) (CFF)
Date received	Apr 17, 2006
Decision date	Jul 6, 2006
Days to decision	80 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Helena Laboratories</b>
Location	Mchenry, IL, US
Contact	PATRICIA FRANKS
510(k) history	280 submissions · 280 cleared · 1978-2013

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k061069/>; 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