

**K894946 PLATELIA RUBELLA IGG KIT**Dec 21, 1989  
140 days to decisionK894946 · Product code: LFX · Microbiology  
Source: <https://www.510kdatabase.net/k894946/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunoabsorbent Assay, Rubella (LFX)
Date received	Aug 3, 1989
Decision date	Dec 21, 1989
Days to decision	140 days
Third-party review	No

**APPLICANT**

---

Company	<b>Kallestad Diag, A Div. of Erbamont, Inc.</b>
Location	Chaska, MN, US
Contact	SUSAN TESMER
510(k) history	58 submissions · 58 cleared · 1987-1991

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k894946/>; 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 29, 2026