

**K983541 HSV 1+2 IGG ELISA TEST**Feb 26, 1999  
140 days to decisionK983541 · Product code: **LGC** · Microbiology  
Source: <https://www.510kdatabase.net/k983541/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunoabsorbent Assay, Herpes Simplex Virus, Non-specific (LGC)
Date received	Oct 9, 1998
Decision date	Feb 26, 1999
Days to decision	140 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Gull Laboratories, Inc.</b>
Location	UT, US
Contact	FRED W RACHFORD
510(k) history	57 submissions · 57 cleared · 1977-1999

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k983541/> 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