

K910953 HSV-2 IGM ELISA TESTMay 28, 1991
82 days to decisionK910953 · Product code: **LGC** · Microbiology
Source: <https://www.510kdatabase.net/k910953/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunoabsorbent Assay, Herpes Simplex Virus, Non-specific (LGC)
Date received	Mar 7, 1991
Decision date	May 28, 1991
Days to decision	82 days
Third-party review	No

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k910953/>; Data sourced from FDA 510(k) public records (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. - Generated June 29, 2026