

K002262 DIAMEDIX IS-HSV 1&2 IGM TEST SYSTEMNov 28, 2000
126 days to decisionK002262 · Product code: **LGC** · Microbiology
Source: <https://www.510kdatabase.net/k002262/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunoabsorbent Assay, Herpes Simplex Virus, Non-specific (LGC)
Date received	Jul 25, 2000
Decision date	Nov 28, 2000
Days to decision	126 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Diamedix Corp.
Location	Miami, FL, US
Contact	LYNNE STIRLING
510(k) history	68 submissions · 68 cleared · 1986-2011

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