

K963645 HERPES GROUP IGG ELISA TEST SYSTEMFeb 4, 1997
145 days to decisionK963645 · Product code: **LGC** · Microbiology
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunoabsorbent Assay, Herpes Simplex Virus, Non-specific (LGC)
Date received	Sep 12, 1996
Decision date	Feb 4, 1997
Days to decision	145 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Armkel, LLC
Location	Mchenry, IL, US
Contact	WILLIAM L BOTELER, JR.
510(k) history	68 submissions · 68 cleared · 1979-2004

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