

K925208 ORTHO HSV ANTIGEN ELISA TEST, MODIFICATIONDec 28, 1992
91 days to decisionK925208 · 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 28, 1992
Decision date	Dec 28, 1992
Days to decision	91 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ortho Diagnostic Systems, Inc.
Location	Carpinteria, CA, US
Contact	KIM W GRAY
510(k) history	126 submissions · 126 cleared · 1981-1997

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