

**K915551 ORTHO HSV ANTIGEN ELISA TEST**Apr 22, 1992  
133 days to decisionK915551 · Product code: **LGC** · Microbiology  
Source: <https://www.510kdatabase.net/k915551/>**SUBMISSION DETAILS**

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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	Dec 11, 1991
Decision date	Apr 22, 1992
Days to decision	133 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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