

K834449 HSV ANTIGEN ELISA KITMay 2, 1984
135 days to decisionK834449 · Product code: **LGC** · Microbiology
Source: <https://www.510kdatabase.net/k834449/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunoabsorbent Assay, Herpes Simplex Virus, Non-specific (LGC)
Date received	Dec 19, 1983
Decision date	May 2, 1984
Days to decision	135 days
Third-party review	No

APPLICANT

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

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