

K911569 EPSTEIN-BARR VIRUS EBNA-IGG ANTIBODY ELISA TESTJun 10, 1991
63 days to decisionK911569 · Product code: **LLM** · Microbiology
Source: <https://www.510kdatabase.net/k911569/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Antigen, Nuclear, Epstein-barr Virus (LLM)
Date received	Apr 8, 1991
Decision date	Jun 10, 1991
Days to decision	63 days
Third-party review	No

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k911569/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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