

**K872541 ORTHO MONOLERT* RAPID ELISA TEST FOR INFECT.
MONO.**May 13, 1988
319 days to decisionK872541 · Product code: **LJN** · Microbiology
Source: <https://www.510kdatabase.net/k872541/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antibody Igm, If, Epstein-barr Virus (LJN)
Date received	Jun 29, 1987
Decision date	May 13, 1988
Days to decision	319 days
Third-party review	No

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k872541/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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