

K963084 OPUS CMV TEST SYSTEM-MODIFICATIONOct 9, 1996
62 days to decisionK963084 · Product code: **LFZ** · Microbiology
Source: <https://www.510kdatabase.net/k963084/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunoabsorbent Assay, Cytomegalovirus (LFZ)
Date received	Aug 8, 1996
Decision date	Oct 9, 1996
Days to decision	62 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Behring Diagnostics, Inc.
Location	Mchenry, IL, US
Contact	NANCY JOHANSEN
510(k) history	145 submissions · 145 cleared · 1976-1997

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