

K901485 ENZYGNOST ANTI-CMV/IGG + IGMMay 20, 1991
417 days to decisionK901485 · Product code: **LFZ** · Microbiology
Source: <https://www.510kdatabase.net/k901485/>**SUBMISSION DETAILS**

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| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Enzyme Linked Immunoabsorbent Assay, Cytomegalovirus (LFZ) |
| Date received | Mar 29, 1990 |
| Decision date | May 20, 1991 |
| Days to decision | 417 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---|
| Company | Behring Diagnostics, Inc. |
| Location | Mchenry, IL, US |
| Contact | JOHN E HUGHES |
| 510(k) history | 145 submissions · 145 cleared · 1976-1997 |

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