

K904456 CYTOMEGALOVIRUS (CMV) ELISAApr 3, 1991
184 days to decisionK904456 · Product code: **LFZ** · Microbiology
Source: <https://www.510kdatabase.net/k904456/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunoabsorbent Assay, Cytomegalovirus (LFZ)
Date received	Oct 1, 1990
Decision date	Apr 3, 1991
Days to decision	184 days
Third-party review	No

APPLICANT

Company	Virotech, Inc.
Location	North Caldwell, NJ, US
Contact	ROBERT SCHIFF
510(k) history	1 submissions · 1 cleared · 1991-1991

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k904456/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 30, 2026