

K884842 CMV-CUBE(TM)Apr 11, 1989
141 days to decisionK884842 · Product code: **LFZ** · Microbiology
Source: <https://www.510kdatabase.net/k884842/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunoabsorbent Assay, Cytomegalovirus (LFZ)
Date received	Nov 21, 1988
Decision date	Apr 11, 1989
Days to decision	141 days
Third-party review	No

APPLICANT

Company	Difco Laboratories, Inc.
Location	Mchenry, IL, US
Contact	ROBERT
510(k) history	121 submissions · 121 cleared · 1979-1997

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k884842/>; 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 May 14, 2026