

K933549 VIDAS CMV IGM ASSAYAug 2, 1994
376 days to decisionK933549 · Product code: **LKQ** · Microbiology
Source: <https://www.510kdatabase.net/k933549/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antibody Igm,if, Cytomegalovirus Virus (LKQ)
Date received	Jul 22, 1993
Decision date	Aug 2, 1994
Days to decision	376 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Biomerieux Vitek, Inc.
Location	Hazelwood, MO, US
Contact	VICKI ANASTASI
510(k) history	49 submissions · 49 cleared · 1992-1998

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k933549/> 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 28, 2026