

**K933389 OPUS CMV-G**Jun 28, 1994  
351 days to decisionK933389 · Product code: **LFZ** · Microbiology  
Source: <https://www.510kdatabase.net/k933389/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunoabsorbent Assay, Cytomegalovirus (LFZ)
Date received	Jul 12, 1993
Decision date	Jun 28, 1994
Days to decision	351 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

---

Company	<b>Pb Diagnostic Systems, Inc.</b>
Location	Westwood, MA, US
Contact	NANCY M JOHANSEN
510(k) history	35 submissions · 35 cleared · 1988-1994

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k933389/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 29, 2026