

**K891081 CMV ELISA TEST SYSTEM**Jun 2, 1989  
93 days to decisionK891081 · Product code: **LFZ** · Microbiology  
Source: <https://www.510kdatabase.net/k891081/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunoabsorbent Assay, Cytomegalovirus (LFZ)
Date received	Mar 1, 1989
Decision date	Jun 2, 1989
Days to decision	93 days
Third-party review	No

**APPLICANT**

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Company	<b>Zeus Scientific, Inc.</b>
Location	McHenry, IL, US
Contact	JERRY W PICKERING
Website	<a href="https://www.zeusscientific.com">https://www.zeusscientific.com</a>
510(k) history	135 submissions · 135 cleared · 1976-2022

Zeus Scientific, Inc. is a chemistry and immunology device manufacturer based in McHenry, US. The company specializes in flexible autoimmune and infectious disease testing solutions. Zeus Scientific has received FDA 510(k) clearances from total submissions since its first clearance in 1976. The company's regulatory portfolio spans microbiology devices and immunology testing systems, including ELISA-based assays and immunofluorescence platforms. The latest clearance on record dates to 2022, reflecting the company's historical contribution to diagnostic device development. ...