

**K983801 THE APTUS (AUTOMATED) APPLICATION OF THE EBV-VCA IGM ELISA TEST SYSTEM. AN ENZYME LINKED IMMUNOSORBENT ASSAY (ELISA) FO**Dec 10, 1998  
43 days to decisionK983801 · Product code: **LSE** · Microbiology  
Source: <https://www.510kdatabase.net/k983801/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Epstein-barr Virus, Other (LSE)
Date received	Oct 28, 1998
Decision date	Dec 10, 1998
Days to decision	43 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Zeus Scientific, Inc.</b>
Location	Mchenry, IL, US
Contact	MARK J KOPNITSKY
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. ...