

**K984133 THE APTUS (AUTOMATED) APPLICATION OF THE EBNA IGG ELISA TEST SYSTEM. AN ENZYME LINKED IMMUNOSORBENT ASSAY (ELISA) FOR TH**Jan 11, 1999  
54 days to decisionK984133 · Product code: LLM · Microbiology  
Source: <https://www.510kdatabase.net/k984133/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Antigen, Nuclear, Epstein-barr Virus (LLM)
Date received	Nov 18, 1998
Decision date	Jan 11, 1999
Days to decision	54 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. ...