

K042092 ATHENA MULTI-LYTE EBV VCA IGM TEST SYSTEMApr 12, 2005
252 days to decisionK042092 · Product code: **LJN** · Microbiology
Source: <https://www.510kdatabase.net/k042092/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antibody Igm, If, Epstein-barr Virus (LJN)
Date received	Aug 3, 2004
Decision date	Apr 12, 2005
Days to decision	252 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Zeus Scientific, Inc.
Location	Mchenry, IL, US
Contact	MARK J KOPNITSKY
Website	https://www.zeusscientific.com
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. ...
