

K992166 THE APTUS (AUTOMATED) APPLICATION OF THE HSV 1/2 IGM ELISA TEST SYSTEM. AN ENZYME LINKED IMMUNOSORBENT ASSAY (ELISA) FORSep 3, 1999
70 days to decisionK992166 · Product code: **LGC** · Microbiology
Source: <https://www.510kdatabase.net/k992166/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunoabsorbent Assay, Herpes Simplex Virus, Non-specific (LGC)
Date received	Jun 25, 1999
Decision date	Sep 3, 1999
Days to decision	70 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. ...