

**K093784 ATHENA MULTI-LYTE TORCH IGG PLUS TEST SYSTEM**Jul 16, 2010  
219 days to decisionK093784 · Product code: **OPM** · Microbiology  
Source: <https://www.510kdatabase.net/k093784/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Multiplex Immunoassay For T. Gondii, Rubella, Cytomegalovirus And Herpes Simplex Virus 1 And 2 (OPM)
Date received	Dec 9, 2009
Decision date	Jul 16, 2010
Days to decision	219 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Zeus Scientific, Inc.</b>
Location	Mchenry, IL, US
Contact	EWA NADOLCZAK
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. ...