

K102283 ZEUS SCIENTIFIC, INC. TREPONEMA PALLIDUM IGG TEST SYSTEMFeb 10, 2011
182 days to decisionK102283 · Product code: **LIP** · Microbiology
Source: <https://www.510kdatabase.net/k102283/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunoabsorption Assay, Treponema Pallidum (LIP)
Date received	Aug 12, 2010
Decision date	Feb 10, 2011
Days to decision	182 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Zeus Scientific, Inc.
Location	Mchenry, IL, US
Contact	EWA NADOLCZAK
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. ...

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Device record: <https://www.510kdatabase.net/k102283/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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