

K991185 BORRELIA BURGdorFERI IGM WESTERN BLOT TEST SYSTEMSep 3, 1999
148 days to decisionK991185 · Product code: **LSR** · Microbiology
Source: <https://www.510kdatabase.net/k991185/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagent, Borrelia Serological Reagent (LSR)
Date received	Apr 8, 1999
Decision date	Sep 3, 1999
Days to decision	148 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Zeus Scientific, Inc.
Location	Mchenry, IL, US
Contact	MARK 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. ...