

**K113397 ZEUS ELISA BORRELIA VLSE-1/PEPC10 IGG/IGM  
TEST SYSTEM**Jul 26, 2012  
252 days to decisionK113397 · Product code: **LSR** · Microbiology  
Source: <https://www.510kdatabase.net/k113397/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagent, Borrelia Serological Reagent (LSR)
Date received	Nov 17, 2011
Decision date	Jul 26, 2012
Days to decision	252 days
Third-party review	No
Summary / Statement	Statement

**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. ...

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k113397/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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