FDA 510(k) Premarket Notification

CLEARED

K191240 ZEUS ELISA Borrelia VlsE1/pepC10 IgG/IgM Test System

Jul 29, 2019
82 days to decision

K191240 · Product code: **LSR** · Microbiology
Source: https://www.510kdatabase.net/k191240/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagent, Borrelia Serological Reagent (LSR)
Date received	May 8, 2019
Decision date	Jul 29, 2019
Days to decision	82 days
Third-party review	No
Summary / Statement	Statement
Other names	ZEUS ELISA Borrelia burgdorferi IgM Test System

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. ...