FDA 510(k) Premarket Notification

K885317 LYME ELISA TEST SYSTEM

CLEARED

Mar 2, 1989
62 days to decision

K885317 · Product code: **LSR** · Microbiology
Source: https://www.510kdatabase.net/k885317/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagent, Borrelia Serological Reagent (LSR)
Date received	Dec 30, 1988
Decision date	Mar 2, 1989
Days to decision	62 days
Third-party review	No

APPLICANT

Company	**Zeus Scientific, Inc.**
Location	Mchenry, IL, US
Contact	DONALD R TOURVILLE
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. ...