

K871246 IFA TEST FOR ANTIBODIES TO BORRELIA BURGENDORFERIAug 25, 1987
151 days to decisionK871246 · Product code: **LSR** · Microbiology
Source: <https://www.510kdatabase.net/k871246/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagent, Borrelia Serological Reagent (LSR)
Date received	Mar 27, 1987
Decision date	Aug 25, 1987
Days to decision	151 days
Third-party review	No

APPLICANT

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