

K230863 ZEUS Solinas Borrelia VlsE1/pepC10 IgG/IgM Test SystemJul 13, 2023
106 days to decisionK230863 · Product code: **LSR** · Microbiology
Source: <https://www.510kdatabase.net/k230863/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagent, Borrelia Serological Reagent (LSR)
Date received	Mar 29, 2023
Decision date	Jul 13, 2023
Days to decision	106 days
Third-party review	No
Summary / Statement	Statement
Other names	ZEUS Solinas Borrelia VlsE1/pepC10 IgG/IgM Control Kit

APPLICANT

Company	Zeus Scientific
Location	Branchburg, NJ, US
Contact	Mark Kopnitsky
510(k) history	5 submissions · 5 cleared · 2023-2025

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