

K252627 Lyme-ID IgG TestNov 14, 2025
86 days to decisionK252627 · Product code: **LSR** · Microbiology
Source: <https://www.510kdatabase.net/k252627/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagent, Borrelia Serological Reagent (LSR)
Date received	Aug 20, 2025
Decision date	Nov 14, 2025
Days to decision	86 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Bio-ID800

APPLICANT

Company	Inanovate, Inc.
Location	Sioux Falls, SD, US
Contact	Aaron Harmon
510(k) history	1 submissions · 1 cleared · 2025-2025

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