

K193051 LIAISON Lyme Total Antibody Plus, LIAISON Lyme Total Antibody Plus Control Set

Jan 29, 2020
89 days to decision

K193051 · Product code: LSR · Microbiology
Source: <https://www.510kdatabase.net/k193051/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagent, Borrelia Serological Reagent (LSR)
Date received	Nov 1, 2019
Decision date	Jan 29, 2020
Days to decision	89 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	DiaSorin, Inc.
Location	Ellicott City, MD, US
Contact	John C. Walter
510(k) history	71 submissions · 70 cleared · 1998-2026

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k193051/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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