

K142038 EUROIMMUN LYME ELISA(IgG/IgM)May 4, 2015
280 days to decisionK142038 · Product code: **LSR** · Microbiology
Source: <https://www.510kdatabase.net/k142038/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagent, Borrelia Serological Reagent (LSR)
Date received	Jul 28, 2014
Decision date	May 4, 2015
Days to decision	280 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Euroimmun US
Location	Morris Plains, NJ, US
Contact	MICHAEL LOCKE
510(k) history	12 submissions · 11 cleared · 2012-2016

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