FDA 510(k) Premarket Notification

K172722 Anti-Borrelia burgdorferi US EUROLINE-WB (IgM)

CLEARED

Dec 10, 2017
90 days to decision

K172722 · Product code: **LSR** · Microbiology
Source: https://www.510kdatabase.net/k172722/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagent, Borrelia Serological Reagent (LSR)
Date received	Sep 11, 2017
Decision date	Dec 10, 2017
Days to decision	90 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Euroimmun Us, Inc.**
Location	Morristown, NJ, US
Contact	Michael A. Locke
510(k) history	19 submissions · 19 cleared · 2009-2020