FDA 510(k) Premarket Notification

K033070 BORRELIA BURGDORFERI IGM ELISA TEST SYSTEM

CLEARED

Nov 26, 2003
58 days to decision

K033070 · Product code: **LSR** · Microbiology
Source: https://www.510kdatabase.net/k033070/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagent, Borrelia Serological Reagent (LSR)
Date received	Sep 29, 2003
Decision date	Nov 26, 2003
Days to decision	58 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Trinity Biotech USA**
Location	Jamestown, NY, US
Contact	Bonnie B DeJoy
510(k) history	11 submissions · 11 cleared · 1999-2014