FDA 510(k) Premarket Notification

CLEARED

K063866 BIOPLEX 2200 SYPHILIS IGG KIT ON THE BIOPLEX 2200 MULTI-ANALYTE DETECTION SYSTEM

Mar 19, 2007
80 days to decision

K063866 · Product code: **LIP** · Microbiology
Source: https://www.510kdatabase.net/k063866/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunoabsorption Assay, Treponema Pallidum (LIP)
Date received	Dec 29, 2006
Decision date	Mar 19, 2007
Days to decision	80 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Bio-Rad Laboratories**
Location	Hauts-De-Seine, FR
Contact	DAVID BHEND
Website	http://www.bio-rad.com
510(k) history	46 submissions · 45 cleared · 2007-2019

Bio-Rad Laboratories is an American biotechnology firm founded in 1952 in Berkeley, California. The company develops and manufactures specialized products for life science research and clinical diagnostics, with operations worldwide. Bio-Rad has received FDA 510(k) clearances from total submissions between 2007 and 2019. The company's cleared devices span chemistry devices, microbiology, and immunology categories, with notable focus on diagnostic control materials and multiplex immunoassay systems. This regulatory record reflects the company's historical activity in the c...