FDA 510(k) Premarket Notification

CLEARED

K170413 BioPlex 2200 Syphilis Total & RPR, BioPlex 2200 Syphilis Total & RPR Calibrator Set, BioPlex 2200 Syphilis Total & RPR Control Set

May 11, 2017
90 days to decision

K170413 · Product code: **LIP** · Microbiology
Source: https://www.510kdatabase.net/k170413/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunoabsorption Assay, Treponema Pallidum (LIP)
Date received	Feb 10, 2017
Decision date	May 11, 2017
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Bio-Rad Laboratories**
Location	Hauts-De-Seine, FR
Contact	Juang Wang
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...