FDA 510(k) Premarket Notification

CLEARED

K170509 BioPlex 2200 ToRC IgM, BioPlex 2200 ToRC IgM Calibrator Set, BioPlex 2200 ToRC IgM Control Set

May 19, 2017
87 days to decision

K170509 · Product code: **PUQ** · Microbiology
Source: https://www.510kdatabase.net/k170509/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Multiplex Flow Immunoassay, T. Gondii, Rubella, Cmv Igm (PUQ)
Date received	Feb 21, 2017
Decision date	May 19, 2017
Days to decision	87 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Bio-Rad Laboratories**
Location	Hauts-De-Seine, FR
Contact	Arlene Carillo
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...