FDA 510(k) Premarket Notification

CLEARED

K092587 BIOPLEX 2200 RUBELLA & CMV IGM KIT ON THE BIOPLEX 2200 MULTI ANALYTE DETECTION SYSTEM

Dec 3, 2010
466 days to decision

K092587 · Product code: **LFX** · Microbiology
Source: https://www.510kdatabase.net/k092587/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunoabsorbent Assay, Rubella (LFX)
Date received	Aug 24, 2009
Decision date	Dec 3, 2010
Days to decision	466 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Bio-Rad Laboratories**
Location	Hauts-De-Seine, FR
Contact	Patricia Klimley
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...