FDA 510(k) Premarket Notification

CLEARED

K041658 BIOPLEX 200 ANA SCREEN ON THE BIOPLEX 2200 MULTI-ANALYTE DETECTION SYSTEM, MODEL BIOPLEX 2200

Dec 20, 2004
185 days to decision

K041658 · Product code: **LKJ** · Immunology
Source: https://www.510kdatabase.net/k041658/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antinuclear Antibody, Antigen, Control (LKJ)
Date received	Jun 18, 2004
Decision date	Dec 20, 2004
Days to decision	185 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Bio-Rad Laboratories, Inc.**
Location	Chaska, MN, US
Contact	CHRISTOPHER BENSTEN
Website	http://www.bio-rad.com
510(k) history	82 submissions · 82 cleared · 1991-2019

Bio-Rad Laboratories, Inc. is an American developer and manufacturer of specialized technological products for life science research and clinical diagnostics. Founded in 1952 in Berkeley, California, the company is based in Hercules, California, with operations worldwide. Bio-Rad has received FDA 510(k) clearances from total submissions between 1991 and 2019. The company's regulatory record reflects a strong focus on chemistry devices, including hemoglobin testing systems, quality control materials, and diagnostic assays. Additional cleared devices span immunology, hemato...