

**K043341 BIOPLEX 2200 ANA SCREEN WITH MEDICAL
DECISION SUPPORT SOFTWARE FOR USE WITH BIOPLEX
2200 MULTI-ANALYTE DETECTION SYSTEM**Oct 27, 2005
328 days to decisionK043341 · Product code: **NVI** · Immunology
Source: <https://www.510kdatabase.net/k043341/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Diagnostic Software, K-nearest Neighbor Algorithm, Autoimmune Disease (NVI)
Date received	Dec 3, 2004
Decision date	Oct 27, 2005
Days to decision	328 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Bio-Rad Laboratories, Inc.
Location	Chaska, MN, US
Contact	CHRISTOPHER BENTSEN
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...