FDA 510(k) Premarket Notification

**CLEARED**

# K062213 BIOPLEX 2200 EBV IGM PANEL ON BIOPLEX 2200 MULTI-ANALYTE DETECTION SYSTEM

Dec 8, 2006
129 days to decision

K062213 · Product code: **LSE** · Microbiology
Source: https://www.510kdatabase.net/k062213/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Epstein-barr Virus, Other (LSE) |
| Date received | Aug 1, 2006 |
| Decision date | Dec 8, 2006 |
| Days to decision | 129 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Bio-Rad Laboratories, Inc.** |
| Location | Chaska, MN, US |
| Contact | DAVID BHEND |
| 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...