

K130162 LIQUID ASSAYED MULTIQUAL PREMIUMMar 1, 2013
37 days to decisionK130162 · Product code: **JJY** · Chemistry
Source: <https://www.510kdatabase.net/k130162/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Multi-analyte Controls, All Kinds (assayed) (JJY) |
| Date received | Jan 23, 2013 |
| Decision date | Mar 1, 2013 |
| Days to decision | 37 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Bio-Rad Laboratories |
| Location | Hauts-De-Seine, FR |
| Contact | SUZANNE PARSONS |
| 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...
