

**K042335 ARCHITECT FREE PSA MASTERCHECK, MODEL 6C07-05**Sep 17, 2004  
18 days to decisionK042335 · Product code: JJY · Immunology  
Source: <https://www.510kdatabase.net/k042335/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Multi-analyte Controls, All Kinds (assayed) (JJY)
Date received	Aug 30, 2004
Decision date	Sep 17, 2004
Days to decision	18 days
Third-party review	No
Summary / Statement	Summary
Other names	ARCHITECT TITAL PSA MASTERCHECK, MODEL 6C06-05

**APPLICANT**

---

Company	<b>Bio-Rad Laboratories, Inc.</b>
Location	Chaska, MN, US
Contact	MARIA ZEBALLOS
Website	<a href="http://www.bio-rad.com">http://www.bio-rad.com</a>
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...

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k042335/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](https://accessdata.fda.gov). - Generated June 18, 2026