

**K041619 BIO CHECK WHOLE BLOOD/PLASMA/SERUM  
MODEL #801116**Dec 17, 2004  
185 days to decisionK041619 · Product code: **MMI** · Chemistry  
Source: <https://www.510kdatabase.net/k041619/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Immunoassay Method, Troponin Subunit (MMI)
Date received	Jun 15, 2004
Decision date	Dec 17, 2004
Days to decision	185 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Biocheck, Inc.</b>
Location	Northridge, CA, US
Contact	ROBIN J HELLEN, M.S.
510(k) history	14 submissions · 14 cleared · 1999-2004

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k041619/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 29, 2026