

**K013062 BIOCHECK HUMAN CARDIAC TROPONIN-I
IMMUNOASSAY TEST KIT**Jan 8, 2002
118 days to decisionK013062 · Product code: **MMI** · Chemistry
Source: <https://www.510kdatabase.net/k013062/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Immunoassay Method, Troponin Subunit (MMI)
Date received	Sep 12, 2001
Decision date	Jan 8, 2002
Days to decision	118 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k013062/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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