

K971817 OLYMPUS CK-MB REAGENTJun 11, 1997
26 days to decisionK971817 · Product code: **JLB** · Chemistry
Source: <https://www.510kdatabase.net/k971817/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Atp And Creatine Kinase (enzymatic), Creatine (JLB)
Date received	May 16, 1997
Decision date	Jun 11, 1997
Days to decision	26 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Olympus America, Inc.
Location	Lake Success, NY, US
Contact	LAURA STORMS-TYLER
510(k) history	149 submissions · 149 cleared · 1994-2012

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