

K070835 OLYMPUS CK-MB REAGENTJun 4, 2007
69 days to decisionK070835 · Product code: **JHY** · Chemistry
Source: <https://www.510kdatabase.net/k070835/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Colorimetric Method, Cpk Or Isoenzymes (JHY)
Date received	Mar 27, 2007
Decision date	Jun 4, 2007
Days to decision	69 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Olympus Life & Material Science Europa GmbH (Irish
Location	Irving, TX, US
Contact	STEPHANIE G SCHWARTZ
510(k) history	3 submissions · 3 cleared · 2007-2007

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