

**K043202 OLYMPUS CREATINE KINASE REAGENT
OSR6179/OSR6279**Dec 23, 2004
35 days to decisionK043202 · Product code: **CGS** · Chemistry
Source: <https://www.510kdatabase.net/k043202/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nad Reduction/nadh Oxidation, Cpk Or Isoenzymes (CGS)
Date received	Nov 18, 2004
Decision date	Dec 23, 2004
Days to decision	35 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k043202/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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