

**K994189 OLYMPUS CREATINE KINASE REAGENT
OSR6179/6279**Jan 20, 2000
38 days to decisionK994189 · Product code: **CGS** · Chemistry
Source: <https://www.510kdatabase.net/k994189/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nad Reduction/nadh Oxidation, Cpk Or Isoenzymes (CGS)
Date received	Dec 13, 1999
Decision date	Jan 20, 2000
Days to decision	38 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Olympus Diagnostica GmbH
Location	Melville, NY, US
Contact	LAURA STORMS-TYLER
510(k) history	4 submissions · 4 cleared · 1998-2000

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k994189/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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