

K922459 OLYMPUS CREATINE KINASE REAGENTJul 13, 1992
48 days to decisionK922459 · Product code: **CGS** · Chemistry
Source: <https://www.510kdatabase.net/k922459/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nad Reduction/nadh Oxidation, Cpk Or Isoenzymes (CGS)
Date received	May 26, 1992
Decision date	Jul 13, 1992
Days to decision	48 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Olympus Corp.
Location	McHenry, IL, US
Contact	LAURA STORMS-TYLER
Website	https://www.olympus-global.com
510(k) history	142 submissions · 140 cleared · 1978-1995

Olympus Corp. is a Japanese optics and imaging manufacturer founded in 1919. The company operates from McHenry, US, and holds approximately 70 percent of the global endoscope market. Olympus has received FDA 510(k) clearances from total submissions between 1978 and 1995. The company's cleared devices span gastroenterology, urology, obstetrics, gynecology, and chemistry specialties. This regulatory record reflects the company's historical focus on endoscopic surgical instruments and related technologies. Notable cleared device categories include resection electrodes, fiber...
