

**K925155 OLYMPUS ASPARTATE AMINOTRANSFERASE  
REAGENT**Jan 26, 1993  
105 days to decisionK925155 · Product code: **CIT** · Chemistry  
Source: <https://www.510kdatabase.net/k925155/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nadh Oxidation/nad Reduction, Ast/sgot (CIT)
Date received	Oct 13, 1992
Decision date	Jan 26, 1993
Days to decision	105 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Olympus Corp.</b>
Location	Mchenry, IL, US
Contact	LAURA STORMS-TYLER
Website	<a href="https://www.olympus-global.com">https://www.olympus-global.com</a>
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...

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Device record: <https://www.510kdatabase.net/k925155/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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