

**K923609 OLYMPUS TOTAL BILIRUBIN REAGENT**Oct 2, 1992  
79 days to decisionK923609 · Product code: **CIG** · Chemistry  
Source: <https://www.510kdatabase.net/k923609/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Diazo Colorimetry, Bilirubin (CIG)
Date received	Jul 15, 1992
Decision date	Oct 2, 1992
Days to decision	79 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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