

**K931939 OLYMPUS CREATININE REAGENT**Sep 21, 1993  
155 days to decisionK931939 · Product code: **CGX** · Chemistry  
Source: <https://www.510kdatabase.net/k931939/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)              |
| Submission type       | Traditional                                     |
| Device classification | Alkaline Picrate, Colorimetry, Creatinine (CGX) |
| Date received         | Apr 19, 1993                                    |
| Decision date         | Sep 21, 1993                                    |
| Days to decision      | 155 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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