

**K911266 MODIFIED PK TP CONTROL**May 7, 1991  
53 days to decisionK911266 · Product code: **GMT** · Microbiology  
Source: <https://www.510kdatabase.net/k911266/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antigens, Ha, Treponema Pallidum (GMT)
Date received	Mar 15, 1991
Decision date	May 7, 1991
Days to decision	53 days
Third-party review	No

**APPLICANT**

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Company	<b>Olympus Corp.</b>
Location	Mchenry, IL, US
Contact	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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