

**K904667 NA NEEDLES**Dec 12, 1990  
58 days to decisionK904667 · Product code: **GDM** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k904667/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Aspiration And Injection, Reusable (GDM)
Date received	Oct 15, 1990
Decision date	Dec 12, 1990
Days to decision	58 days
Third-party review	No

**APPLICANT**

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