

**K011484 OLYMPUS INJECTOR NM-4-1, NM-5-1, NM-6-1, NM-7-1,  
NM-8-1, NM-9-1**Aug 10, 2001  
88 days to decisionK011484 · Product code: **FBK** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k011484/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Injection Needle, Gastroenterology-urology (FBK)
Date received	May 14, 2001
Decision date	Aug 10, 2001
Days to decision	88 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Olympus Optical Co., Ltd.</b>
Location	Melville, NY, US
Contact	LAURA STORMS-TYLER
Website	<a href="http://www.olympus-global.com/">http://www.olympus-global.com/</a>
510(k) history	22 submissions · 22 cleared · 2000-2003

Olympus Optical Co., Ltd. is a global medical device manufacturer headquartered in Melville, US. The company specializes in endoscopic and surgical imaging technologies for minimally invasive procedures. Olympus received FDA 510(k) clearances from total submissions between 2000 and 2003. The company's cleared devices span multiple surgical specialties, with particular strength in endoscopic visualization systems for gastroenterology, urology, otolaryngology, and general surgery. Notable cleared products include bronchofiberscopes, gastrovideoscopes, cystofiberscopes, and ...

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