

**K021179 DISPOSABLE GUIDEWIRE, MODELS G-205-3545S & G-205-3545A**Jul 5, 2002  
81 days to decisionK021179 · Product code: **OCY** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k021179/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Guidewire, Gastroenterology-urology (OCY)
Date received	Apr 15, 2002
Decision date	Jul 5, 2002
Days to decision	81 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 ...