

**K014166 UHI-3 HIGH FLOW INSUFFLATION UNIT**Jun 25, 2002  
188 days to decisionK014166 · Product code: **HIF** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k014166/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Insufflator, Laparoscopic (HIF)
Date received	Dec 19, 2001
Decision date	Jun 25, 2002
Days to decision	188 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

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 ...

---