

**K031347 ULTRASONIC GASTROVIDEOSCOPE, TYPE UC160P-AT8 AND UCT160-AT8**May 9, 2003  
10 days to decisionK031347 · Product code: **ODG** · Radiology  
Source: <https://www.510kdatabase.net/k031347/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Ultrasound System, Gastroenterology-urology (ODG)
Date received	Apr 29, 2003
Decision date	May 9, 2003
Days to decision	10 days
Third-party review	Yes
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 ...