

**K010591 OLYMPUS EU-C60 EUS EXERA COMPACT
ENDOSCOPIC ULTRASOUND CENTER**Mar 15, 2001
15 days to decisionK010591 · Product code: **ODG** · Radiology
Source: <https://www.510kdatabase.net/k010591/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Ultrasound System, Gastroenterology-urology (ODG)
Date received	Feb 28, 2001
Decision date	Mar 15, 2001
Days to decision	15 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	Olympus Optical Co., Ltd.
Location	Melville, NY, US
Contact	TSUYOSHI YANAI
Website	http://www.olympus-global.com/
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 ...