

K031305 OLYMPUS ULTRASONIC SURGICAL SYSTEMSep 23, 2003
152 days to decisionK031305 · Product code: **LFL** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k031305/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Ultrasonic Surgical (LFL)
Date received	Apr 24, 2003
Decision date	Sep 23, 2003
Days to decision	152 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Olympus Optical Co., Ltd.
Location	Melville, NY, US
Contact	TINA STEFFANIE-OAK
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 ...
