

K915857 FLEXIBLE TIP THORACOSCOPE/LAPAROSCOPEMar 11, 1994
805 days to decisionK915857 · Product code: **HET** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k915857/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laparoscope, Gynecologic (and Accessories) (HET)
Date received	Dec 27, 1991
Decision date	Mar 11, 1994
Days to decision	805 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Olympus Corp.
Location	Mchenry, IL, US
Contact	DANIEL J DILLON
Website	https://www.olympus-global.com
510(k) history	142 submissions · 140 cleared · 1978-1995

Olympus Corp. is a Japanese optics and imaging manufacturer founded in 1919. The company operates from McHenry, US, and holds approximately 70 percent of the global endoscope market. Olympus has received FDA 510(k) clearances from total submissions between 1978 and 1995. The company's cleared devices span gastroenterology, urology, obstetrics, gynecology, and chemistry specialties. This regulatory record reflects the company's historical focus on endoscopic surgical instruments and related technologies. Notable cleared device categories include resection electrodes, fiber...
