

K852980 OCS-2 COLPOSCOPEOct 23, 1985
100 days to decisionK852980 · Product code: **HEX** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k852980/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Colposcope (and Colpomicroscope) (HEX)
Date received	Jul 15, 1985
Decision date	Oct 23, 1985
Days to decision	100 days
Third-party review	No

APPLICANT

Company	Olympus Corp.
Location	Mchenry, IL, US
Contact	WALTER J SEIDL
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...
