

K931994 RESECTOSCOPE SHEATHFeb 17, 1994
300 days to decisionK931994 · Product code: **HIH** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k931994/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hysteroscope (and Accessories) (HIH)
Date received	Apr 23, 1993
Decision date	Feb 17, 1994
Days to decision	300 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Olympus Corp.
Location	Mchenry, IL, US
Contact	BARRY SANDS
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...
