

K903842 ST-E1 OVERTUBEJan 23, 1991
155 days to decisionK903842 · Product code: **FED** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k903842/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Access Overtube, Gastroenterology-urology (FED)
Date received	Aug 21, 1990
Decision date	Jan 23, 1991
Days to decision	155 days
Third-party review	No

APPLICANT

Company	Olympus Corp.
Location	Mchenry, IL, US
Contact	DANIEL 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...
