

**K942338 OLYMPUS PF-8P OES PANCREATO FIBERSCOPE
AND ACCESSORIES**Nov 30, 1994
198 days to decisionK942338 · Product code: FDT · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k942338/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Duodenoscope And Accessories, Flexible/rigid (FDT)
Date received	May 16, 1994
Decision date	Nov 30, 1994
Days to decision	198 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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