CLEARED

K002231 LF-DP GASTROINTESTINAL AND SIGMOID FIBERSCOPE, ACCESSORIES AND ANCILLARY EQUIPMENT

Jan 30, 2001
190 days to decision

K002231 · Product code: **FDS** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k002231/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gastroscope And Accessories, Flexible/rigid (FDS)
Date received	Jul 24, 2000
Decision date	Jan 30, 2001
Days to decision	190 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Olympus Optical Co., Ltd.**
Location	Melville, NY, US
Contact	LAURA STORMS-TYLER
Website	http://www.olympus-global.com/
510(k) history	22 submissions · 22 cleared · 2000-2003

Olympus Optical Co., Ltd. is a global medical device manufacturer headquartered in Melville, US. The company specializes in endoscopic and surgical imaging technologies for minimally invasive procedures. Olympus received FDA 510(k) clearances from total submissions between 2000 and 2003. The company's cleared devices span multiple surgical specialties, with particular strength in endoscopic visualization systems for gastroenterology, urology, otolaryngology, and general surgery. Notable cleared products include bronchofiberscopes, gastrovideoscopes, cystofiberscopes, and ...