FDA 510(k) Premarket Notification

K882061 OLYMPUS GF-UM3/EU-M3

CLEARED

Nov 15, 1988
183 days to decision

K882061 · Product code: **GDB** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k882061/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscope, Fiber Optic (GDB)
Date received	May 16, 1988
Decision date	Nov 15, 1988
Days to decision	183 days
Third-party review	No

APPLICANT

Company	**Olympus Corp.**
Location	Mchenry, IL, US
Contact	HIROYUKI SASA
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...