FDA 510(k) Premarket Notification

K790071 ENDOSCOPE AND ACCESSORIES

CLEARED

Apr 2, 1979
81 days to decision

K790071 · Product code: **GCP** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k790071/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscope, Ac-powered And Accessories (GCP)
Date received	Jan 11, 1979
Decision date	Apr 2, 1979
Days to decision	81 days
Third-party review	No

APPLICANT

Company	**Olympus Corp.**
Location	Mchenry, IL, US
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...

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k790071/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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