FDA 510(k) Premarket Notification

K852888 OLYMPUS RIGID URETERORENOSCOPE

CLEARED

Aug 21, 1985
43 days to decision

K852888 · Product code: **FGB** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k852888/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ureteroscope And Accessories, Flexible/rigid (FGB)
Date received	Jul 9, 1985
Decision date	Aug 21, 1985
Days to decision	43 days
Third-party review	No

APPLICANT

Company	**Olympus Corp.**
Location	Mchenry, IL, US
Contact	SCOTT J SOLANO
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...