FDA 510(k) Premarket Notification

CLEARED

K181451 URETERO-RENO VIDEOSCOPE OLYMPUS URF-V3/V3R, URETERO-RENO FIBERSCOPE OLYMPUS URF-P7/P7R

Jan 16, 2019
229 days to decision

K181451 · Product code: **FGB** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k181451/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ureteroscope And Accessories, Flexible/rigid (FGB)
Date received	Jun 1, 2018
Decision date	Jan 16, 2019
Days to decision	229 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Olympus Medical Systems Corp.**
Location	Hachiochi-Shi, JP
Contact	Toshiyuki Nakajima
Website	https://www.olympus-global.com
510(k) history	102 submissions · 102 cleared · 2012-2026

Olympus Medical Systems Corp. is a global medical device manufacturer headquartered in Hachiochi-Shi, Japan. The company specializes in endoscopic imaging systems and therapeutic devices for minimally invasive procedures. Olympus has received FDA 510(k) clearances from total submissions since 2012. The company's regulatory portfolio is dominated by Gastroenterology & Urology devices, including endoscopes, hemostatic forceps, biopsy instruments, and sphincterotomes. The latest clearance in 2026 reflects continued active development and market engagement. Recent cleared dev...

REGULATORY CONSULTANT

Consulting firm	**Olympus Surgical Technologies America**
Contact	Sheri L. Musgnung

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov