FDA 510(k) Premarket Notification

K250432 Colonovideoscope (CF-EZ1500DL)

CLEARED

May 15, 2025
90 days to decision

K250432 · Product code: **FDF** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k250432/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Colonoscope And Accessories, Flexible/rigid (FDF)
Date received	Feb 14, 2025
Decision date	May 15, 2025
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Colonovideoscope (CF-EZ1500DI); Gastrointestinal Videoscope (GIF-EZ1500)

APPLICANT

Company	**Olympus Medical Systems Corporation**
Location	Melville, NY, US
Contact	Shinichiro Kawachi
510(k) history	81 submissions · 81 cleared · 2004-2026

REGULATORY CONSULTANT

Consulting firm	**Olympus Corporation of the Americas**
Contact	Teffany Hutto

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