

K261183 EVIS EUS Ultrasound Gastrointestinal Videoscope (Olympus GF-UE190)

Jul 31, 2026
112 days to decision

K261183 · Product code: ODG · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k261183/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Ultrasound System, Gastroenterology-urology (ODG)
Date received	Apr 10, 2026
Decision date	Jul 31, 2026
Days to decision	112 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Olympus Medical Systems Corporation
Location	Melville, NY, US
Contact	Shinichiro Kawachi
510(k) history	83 submissions · 83 cleared · 2004-2026

REGULATORY CONSULTANT

Consulting firm	Olympus Corporation of the Americas
Contact	Deborah Kipp

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