

**K222584 EVIS X1 VIDEO SYSTEM CENTER OLYMPUS CV-1500,
COLONOVideoscope OLYMPUS CF-HQ1100DL/I,
GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF-1100**Apr 26, 2023
243 days to decisionK222584 · Product code: FET · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k222584/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Video Imaging System/component, Gastroenterology-urology (FET)
Date received	Aug 26, 2022
Decision date	Apr 26, 2023
Days to decision	243 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	81 submissions · 81 cleared · 2004-2026

REGULATORY CONSULTANT

Consulting firm	Olympus Corporation of the Americas
Contact	Darlene Hull

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

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