

**K221683 CYSTO-NEPHRO VIDEOSCOPE (OLYMPUS CYF-V2), CYSTO-NEPHRO VIDEOSCOPE (OLYMPUS CYF-V2R), CYSTO-NEPHRO VIDEOSCOPE (OLYMPUS CYF-VH) and CYSTO-NEPHRO VIDEOSCOPE (OLYMPUS CYF-VHR)**Jan 20, 2023  
224 days to decisionK221683 · Product code: **FAJ** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k221683/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cystoscope And Accessories, Flexible/rigid (FAJ)
Date received	Jun 10, 2022
Decision date	Jan 20, 2023
Days to decision	224 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Olympus Corporation of the Americas</b>
Contact	Teffany Hutto

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k221683/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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