**CLEARED**

Jan 20, 2023
224 days to decision

# 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)

K221683 · Product code: **FAJ** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k221683/

## SUBMISSION DETAILS

| | |
|---|---|
| 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

| | |
|---|---|
| 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