FDA 510(k) Premarket Notification

# K221557 Visera Hysterovideoscope Olympus HYF Type V

**CLEARED**

Sep 2, 2022
94 days to decision

K221557 · Product code: **HIH** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k221557/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Hysteroscope (and Accessories) (HIH) |
| Date received | May 31, 2022 |
| Decision date | Sep 2, 2022 |
| Days to decision | 94 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 | Toshio Nakamura |
| 510(k) history | 81 submissions · 81 cleared · 2004-2026 |

## REGULATORY CONSULTANT

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|---|---|
| Consulting firm | **Olympus Corporation of the Americas** |
| Contact | Gary Brennan |

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