

**K243527 High Flow Insufflation Unit (UHI-4)**Jan 13, 2025  
60 days to decisionK243527 · Product code: **HIF** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k243527/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Insufflator, Laparoscopic (HIF)
Date received	Nov 14, 2024
Decision date	Jan 13, 2025
Days to decision	60 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

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**

---

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](https://accessdata.fda.gov)

---

510k Database - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k243527/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](https://accessdata.fda.gov). - Generated May 13, 2026