

**K213207 Sheath, Stopcock Accessory**Dec 22, 2021  
84 days to decisionK213207 · Product code: **HIH** · Obstetrics & Gynecology  
Source: <https://www.510kdatabase.net/k213207/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hysteroscope (and Accessories) (HIH)
Date received	Sep 29, 2021
Decision date	Dec 22, 2021
Days to decision	84 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Olympus Winter &amp; Ibe GmbH</b>
Location	Melville, NY, US
Contact	Katharina Campbell
510(k) history	42 submissions · 42 cleared · 1997-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>Olympus Corporation of the Americas (Oca)</b>
Contact	Jonathan Gilbert

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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