

**K202445 Hystero-V Hysteroscope**Nov 23, 2021  
454 days to decisionK202445 · Product code: **HIH** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k202445/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hysteroscope (and Accessories) (HIH)
Date received	Aug 26, 2020
Decision date	Nov 23, 2021
Days to decision	454 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>HysteroVue, Inc.</b>
Location	Bellevue, WA, US
Contact	Thomas Lawson
510(k) history	1 submissions · 1 cleared · 2021-2021

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k202445/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 26, 2026