

**K252012 SPY Cystoscope/Hysteroscope**Jul 18, 2025  
21 days to decisionK252012 · Product code: **HIH** · Obstetrics & Gynecology  
Source: <https://www.510kdatabase.net/k252012/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Hysteroscope (and Accessories) (HIH)
Date received	Jun 27, 2025
Decision date	Jul 18, 2025
Days to decision	21 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Stryker Endoscopy</b>
Location	San Jose, CA, US
Contact	Irina Glazkova
Website	<a href="https://www.stryker.com">https://www.stryker.com</a>
510(k) history	99 submissions · 99 cleared · 1993-2026

Stryker Endoscopy is a medical device manufacturer based in San Jose, US. The company specializes in endoscopic and surgical imaging systems for minimally invasive procedures. Stryker Endoscopy has received FDA 510(k) clearances from total submissions since its first clearance in 1993. The company maintains active regulatory status, with its latest clearance in 2026. Its portfolio spans General & Plastic Surgery devices, orthopedic surgical tools, and obstetric and gynecologic instruments. Recent cleared devices include advanced imaging systems such as 4K camera platforms...

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k252012/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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