

K233635 SPY Cystoscope/HysteroscopeFeb 12, 2024
91 days to decisionK233635 · Product code: **HIH** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k233635/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hysteroscope (and Accessories) (HIH)
Date received	Nov 13, 2023
Decision date	Feb 12, 2024
Days to decision	91 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Stryker Endoscopy
Location	San Jose, CA, US
Contact	Michelle Ross
Website	https://www.stryker.com
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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Device record: <https://www.510kdatabase.net/k233635/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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