

**K190639 Endosee System**May 15, 2019  
63 days to decisionK190639 · Product code: **HIH** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k190639/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Hysteroscope (and Accessories) (HIH)
Date received	Mar 13, 2019
Decision date	May 15, 2019
Days to decision	63 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>CooperSurgical, Inc.</b>
Location	Mountain View, CA, US
Contact	Christine Kupchick
510(k) history	41 submissions · 40 cleared · 1991-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k190639/> 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 14, 2026