

**K954311 KOH COLPOTOMIZER SYSTEM**Nov 19, 1996  
431 days to decisionK954311 · Product code: **HEW** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k954311/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Culdoscope (and Accessories) (HEW)
Date received	Sep 15, 1995
Decision date	Nov 19, 1996
Days to decision	431 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>CooperSurgical, Inc.</b>
Location	Mountain View, CA, US
Contact	MARY M MCNAMARA
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/k954311/> 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 June 28, 2026