

**K943662 LAPARASCOPE**May 25, 1995  
301 days to decisionK943662 · Product code: **HET** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k943662/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laparoscope, Gynecologic (and Accessories) (HET)
Date received	Jul 28, 1994
Decision date	May 25, 1995
Days to decision	301 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Pollux Endoscopy, Inc.</b>
Location	Sunrise, FL, US
510(k) history	4 submissions · 4 cleared · 1995-2000

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k943662/>; 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 21, 2026