

**K935634 WALLACH LEEP PROCEDURE KIT**Jul 20, 1994  
239 days to decisionK935634 · Product code: **HGI** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k935634/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrocautery, Gynecologic (and Accessories) (HGI)
Date received	Nov 23, 1993
Decision date	Jul 20, 1994
Days to decision	239 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Wallach Surgical Devices, Inc.</b>
Location	Walker, MI, US
Contact	RAYMOND A WILEY
510(k) history	27 submissions · 27 cleared · 1981-2002

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k935634/> 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 20, 2026