

**K940316 HYSTERSCOPE**Nov 16, 1995  
661 days to decisionK940316 · Product code: **HIH** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k940316/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hysteroscope (and Accessories) (HIH)
Date received	Jan 24, 1994
Decision date	Nov 16, 1995
Days to decision	661 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Stephen Chakoff, Inc.</b>
Location	Miami, FL, US
Contact	FRANK GOLDFARB
510(k) history	16 submissions · 16 cleared · 1993-1995

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k940316/> 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 29, 2026