

**K921942 HYSTEROSCOPE (AND ACCESSORIES)**Jun 24, 1994  
791 days to decisionK921942 · Product code: **HIH** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k921942/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hysteroscope (and Accessories) (HIH)
Date received	Apr 24, 1992
Decision date	Jun 24, 1994
Days to decision	791 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Optimed Technologies, Inc.</b>
Location	Irvine, CA, US
Contact	RONALD J EHMTSEN
510(k) history	15 submissions · 15 cleared · 1988-1997

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k921942/> 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