

**K951946 HYSTEROSYS FLEXIBLE HYSTEROSCOPE**Nov 20, 1995  
208 days to decisionK951946 · Product code: **HIH** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k951946/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hysteroscope (and Accessories) (HIH)
Date received	Apr 26, 1995
Decision date	Nov 20, 1995
Days to decision	208 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Ovamed Corp.</b>
Location	Sunnyvale, CA, US
Contact	CHRISTINE DECARIA
510(k) history	5 submissions · 5 cleared · 1995-1995

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k951946/> 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