

**K974297 GALILEO DISPOSABLE HYSTEROSCOPES**Feb 13, 1998  
88 days to decisionK974297 · Product code: **HIH** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k974297/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hysteroscope (and Accessories) (HIH)
Date received	Nov 17, 1997
Decision date	Feb 13, 1998
Days to decision	88 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Netoptix Corp.</b>
Location	Sturbridge, MA, US
Contact	MARY MCNAMARA-CULLINANE
510(k) history	4 submissions · 4 cleared · 1997-1998

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k974297/> 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