

**K981958 LEISEGANG VIDEO COLPOSCOPE**Oct 19, 1998  
137 days to decisionK981958 · Product code: **HEX** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k981958/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Colposcope (and Colpomicroscope) (HEX)
Date received	Jun 4, 1998
Decision date	Oct 19, 1998
Days to decision	137 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/k981958/> 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