

**K090324 ULTRASIGHT HD DIGITAL COLPOSCOPY WITH  
IMAGESENSE TECHNOLOGY**Dec 20, 2010  
679 days to decisionK090324 · Product code: **HEX** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k090324/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Colposcope (and Colpomicroscope) (HEX)
Date received	Feb 9, 2009
Decision date	Dec 20, 2010
Days to decision	679 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Sti Medical Systems</b>
Location	Honolulu, HI, US
Contact	ROLF WOLTERS
510(k) history	2 submissions · 2 cleared · 2008-2010

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k090324/> Data sourced from FDA 510(k) public records (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 20, 2026