

**K110147 ULTRASIGHTHD C31 WITH IMAGESENSE AND  
REMOTE VIEWER TELEMEDICINE**

Apr 8, 2011  
80 days to decision

K110147 · Product code: **HEX** · Obstetrics & Gynecology  
Source: <https://www.510kdatabase.net/k110147/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Colposcope (and Colpomicroscope) (HEX)
Date received	Jan 18, 2011
Decision date	Apr 8, 2011
Days to decision	80 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Sti Medical Systems, LLC</b>
Location	Aiea, HI, US
Contact	ROLF WOLTERS
510(k) history	2 submissions · 2 cleared · 2011-2011

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k110147/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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