

**K181034 Pocket Colposcope System**Sep 21, 2018  
156 days to decisionK181034 · Product code: **HEX** · Obstetrics & Gynecology  
Source: <https://www.510kdatabase.net/k181034/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Colposcope (and Colpomicroscope) (HEX)
Date received	Apr 18, 2018
Decision date	Sep 21, 2018
Days to decision	156 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Hadleigh Health Technologies, LLC</b>
Location	San Rafael, CA, US
Contact	Robert Miros
510(k) history	1 submissions · 1 cleared · 2018-2018

**REGULATORY CONSULTANT**

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Consulting firm	<b>University of Utah</b>
Contact	Spencer Walker

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k181034/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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