

**K181909 Luminelle DTx Hysteroscopy System**Aug 16, 2018  
30 days to decisionK181909 · Product code: **FAJ** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k181909/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cystoscope And Accessories, Flexible/rigid (FAJ)
Date received	Jul 17, 2018
Decision date	Aug 16, 2018
Days to decision	30 days
Third-party review	Yes
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Uvision360, Inc.</b>
Location	Raleigh, NC, US
Contact	Allison London Brown
510(k) history	4 submissions · 4 cleared · 2018-2021

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k181909/> 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 May 27, 2026