

**K190827 Luminelle DTx Hysteroscopy System, Luminelle 360
Rotatable Sterile Disposable Sheath Rigid**Jun 6, 2019
66 days to decisionK190827 · Product code: **HIH** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k190827/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Hysteroscope (and Accessories) (HIH)
Date received	Apr 1, 2019
Decision date	Jun 6, 2019
Days to decision	66 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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