

**K192278 Luminelle DTx Hysteroscopy System, Luminelle Dx
360 Rotatable Disposable Sheath (Diagnostic)**

Nov 1, 2019
71 days to decision

K192278 · Product code: **HIH** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k192278/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Hysteroscope (and Accessories) (HIH)
Date received	Aug 22, 2019
Decision date	Nov 1, 2019
Days to decision	71 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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k192278/>; 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. - Generated May 27, 2026