FDA 510(k) Premarket Notification

**CLEARED**

# 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 |