FDA 510(k) Premarket Notification

K210512 LUMINELLE DTx System

CLEARED

Jun 30, 2021
127 days to decision

K210512 · Product code: **FAJ** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k210512/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cystoscope And Accessories, Flexible/rigid (FAJ)
Date received	Feb 23, 2021
Decision date	Jun 30, 2021
Days to decision	127 days
Third-party review	No
Combination product	No
PCCP authorized	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

REGULATORY CONSULTANT

Consulting firm	**MethodSense, Inc.**
Contact	Rita King

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