FDA 510(k) Premarket Notification

K181909 Luminelle DTx Hysteroscopy System

CLEARED

Aug 16, 2018
30 days to decision

K181909 · Product code: **FAJ** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k181909/

SUBMISSION DETAILS

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

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