FDA 510(k) Premarket Notification

K191780 AP50/30 Insufflator with Insuflow Port

CLEARED

Aug 28, 2019
57 days to decision

K191780 · Product code: **HIF** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k191780/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Insufflator, Laparoscopic (HIF)
Date received	Jul 2, 2019
Decision date	Aug 28, 2019
Days to decision	57 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Lexion Medical, LLC**
Location	St. Paul, MN, US
Contact	Bernard Horwath
510(k) history	13 submissions · 13 cleared · 2007-2019

REGULATORY CONSULTANT

Consulting firm	**Hrg**
Contact	Bernard Horwath

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