

K190187 Gynoscope SystemMay 8, 2019
96 days to decisionK190187 · Product code: **HEX** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k190187/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Colposcope (and Colpomicroscope) (HEX)
Date received	Feb 1, 2019
Decision date	May 8, 2019
Days to decision	96 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Illumigyn , Ltd.
Location	Neve Ilan, IL
Contact	Lior Greenstein
510(k) history	1 submissions · 1 cleared · 2019-2019

REGULATORY CONSULTANT

Consulting firm	A. Stein Regulatory Affairs Consulting , Ltd.
Contact	Ahava Stein

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

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