FDA 510(k) Premarket Notification

K190190 WV1 Endoscope

CLEARED

Nov 1, 2019
273 days to decision

K190190 · Product code: **HET** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k190190/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laparoscope, Gynecologic (and Accessories) (HET)
Date received	Feb 1, 2019
Decision date	Nov 1, 2019
Days to decision	273 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**270surgical , Ltd.**
Location	Natanya, IL
Contact	Avi Levy
510(k) history	2 submissions · 2 cleared · 2019-2021

REGULATORY CONSULTANT

Consulting firm	**Hogan Lovells US LLP**
Contact	Janice Hogan

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k190190/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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