FDA 510(k) Premarket Notification

K182764 Biop Digital Colposcope

CLEARED

Nov 27, 2018
60 days to decision

K182764 · Product code: **HEX** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k182764/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Colposcope (and Colpomicroscope) (HEX)
Date received	Sep 28, 2018
Decision date	Nov 27, 2018
Days to decision	60 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Biop Medical , Ltd.**
Location	Ramat-Gan, IL
Contact	Ilan Landesman
510(k) history	1 submissions · 1 cleared · 2018-2018

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/k182764/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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