FDA 510(k) Premarket Notification

K190277 ProVate Vaginal Support

CLEARED

Jul 8, 2019
150 days to decision

K190277 · Product code: **HHW** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k190277/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pessary, Vaginal (HHW)
Date received	Feb 8, 2019
Decision date	Jul 8, 2019
Days to decision	150 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Contipi Medical , Ltd.**
Location	Caesarea, IL
Contact	Tsvia Erlich
510(k) history	1 submissions · 1 cleared · 2019-2019

REGULATORY CONSULTANT

Consulting firm	**Hogan Lovells US Lpp**
Contact	Jonathan S. Kahan

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

CLINICAL EVIDENCE - NCT02239133

R&D Supporting Pilot Study for the Assessment of the Safety and Effectiveness of the ProVATE (ProTIPI) Vaginal Pessary

Status	Unknown - *No results published to ClinicalTrials.gov*
Enrollment	44 patients (actual)
Study sites	3 sites
Condition studied	Pelvic Organ Prolapse
Primary purpose	Treatment
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Sep 1, 2016
Sponsor	ConTIPI Medical (Industry)

Primary outcome

Degree of prolapse and POP symptoms following ProVATE device insertion, compared to the degree of prolapse prior to the insertion of the ProVATE device (by vaginal examination)

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT02239133