

K203377 VR101 Lubricating Intravaginal RingMay 20, 2021
184 days to decisionK203377 · Product code: **QPD** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k203377/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Personal Lubricant Ring (QPD)
Date received	Nov 17, 2020
Decision date	May 20, 2021
Days to decision	184 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	J3 Bioscience, Inc.
Location	Salt Lake City, UT, US
Contact	R. Tyler McCabe
510(k) history	1 submissions · 1 cleared · 2021-2021

CLINICAL EVIDENCE - NCT02029053**Preliminary Study of a Vaginal Lubrication Ring to Treat the Symptoms of Vaginal Dryness**

Status	Completed - <i>No results published to ClinicalTrials.gov</i>
Enrollment	21 patients (actual)
Study sites	1 site
Condition studied	Menopausal and Perimenopausal Disorder, Unspecified; Atrophic Vaginitis
Primary purpose	Supportive_care
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	May 1, 2014
Sponsor	J3 Bioscience, Inc. (Industry)

Primary outcome

Vaginal lubrication/moisturization

Secondary outcome

Comfort and fit of intravaginal ring

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT02029053