

K202017 Passion Natural Water Based LubricantJan 8, 2021
171 days to decisionK202017 · Product code: **NUC** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k202017/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lubricant, Personal (NUC)
Date received	Jul 21, 2020
Decision date	Jan 8, 2021
Days to decision	171 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Xr, LLC
Location	Huntington Beach, CA, US
Contact	Louie Goryoka
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Med-Device Consulting, Inc.
Contact	Louie Goryoka

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k202017/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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