

K221328 Bloomi Smooth Water Based LubricantAug 4, 2022
90 days to decisionK221328 · Product code: **NUC** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k221328/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lubricant, Personal (NUC)
Date received	May 6, 2022
Decision date	Aug 4, 2022
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	The Bloomi Inc..
Location	Alamo, CA, US
Contact	Rebecca Story
510(k) history	2 submissions · 2 cleared · 2022-2022

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.gov510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k221328/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026