

K222175 Bloomi Delight Oil-Based Personal LubricantNov 15, 2022
117 days to decisionK222175 · Product code: **NUC** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k222175/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lubricant, Personal (NUC)
Date received	Jul 21, 2022
Decision date	Nov 15, 2022
Days to decision	117 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
Contact	Louie Goryoka

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

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