

K181078 The Sex GelSep 10, 2018
139 days to decisionK181078 · Product code: **NUC** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k181078/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lubricant, Personal (NUC)
Date received	Apr 24, 2018
Decision date	Sep 10, 2018
Days to decision	139 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Necessaire, Inc.
Location	Manhattan Beach, CA, US
Contact	Randi Christiansen Stanley
510(k) history	1 submissions · 1 cleared · 2018-2018

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](https://accessdata.fda.gov)

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