

K191052 HyaloGYN Vaginal Moisturizing SuppositoriesJan 9, 2020
265 days to decisionK191052 · Product code: **NUC** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k191052/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lubricant, Personal (NUC)
Date received	Apr 19, 2019
Decision date	Jan 9, 2020
Days to decision	265 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Fidia Farmaceutici S.P.A.
Location	Abano Terme, IT
Contact	Giuseppina Lo Castro
510(k) history	3 submissions · 3 cleared · 2010-2020

REGULATORY CONSULTANT

Consulting firm	Fidia Pharma USA, Inc.
Contact	Vivian Kelly

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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