

K193444 Vagisan MoistCream CremolumDec 4, 2020
358 days to decisionK193444 · Product code: **NUC** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k193444/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lubricant, Personal (NUC)
Date received	Dec 12, 2019
Decision date	Dec 4, 2020
Days to decision	358 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Dr. August Wolff GmbH & Co. KG Arzneimittel
Location	Bielefeld, DE
Contact	Thomas Flototto
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	Emergo Global Consulting, LLC
Contact	Oliver Eikenberg

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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