

K201612 Elegant 2 in 1 Vaginal Moisturizer, Elegant Advanced 5Sep 2, 2021
444 days to decisionK201612 · Product code: **NUC** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k201612/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lubricant, Personal (NUC)
Date received	Jun 15, 2020
Decision date	Sep 2, 2021
Days to decision	444 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Viramal Limited
Location	London, GB
Contact	Simona Fiore
510(k) history	2 submissions · 2 cleared · 2021-2023

REGULATORY CONSULTANT

Consulting firm	Biologics Consulting Group, Inc.
Contact	Joshua Crist

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k201612/> 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