

K192982 KY Grosz UltraGelApr 14, 2020
172 days to decisionK192982 · Product code: **NUC** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k192982/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lubricant, Personal (NUC)
Date received	Oct 25, 2019
Decision date	Apr 14, 2020
Days to decision	172 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Rb Health (Us), LLC
Location	Parsippany, NJ, US
Contact	Elizabeth Viguerie
510(k) history	14 submissions · 14 cleared · 2019-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k192982/> 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 25, 2026