

**K231794 Elegant™ Advanced CompHort**Dec 22, 2023  
185 days to decisionK231794 · Product code: **NUC** · Obstetrics & Gynecology  
Source: <https://www.510kdatabase.net/k231794/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Lubricant, Personal (NUC)          |
| Date received         | Jun 20, 2023                       |
| Decision date         | Dec 22, 2023                       |
| Days to decision      | 185 days                           |
| Third-party review    | No                                 |
| Combination product   | No                                 |
| PCCP authorized       | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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

**REGULATORY CONSULTANT**

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|-----------------|---|
| Consulting firm | <b>Biologics Consulting Group, Inc.</b> |
| Contact         | Joshua Crist                            |

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k231794/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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