

**K232047 VIVACE**Mar 28, 2024  
262 days to decisionK232047 · Product code: **HGX** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k232047/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Pump, Breast, Powered (HGX)        |
| Date received         | Jul 10, 2023                       |
| Decision date         | Mar 28, 2024                       |
| Days to decision      | 262 days                           |
| Third-party review    | No                                 |
| Combination product   | No                                 |
| PCCP authorized       | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Unimom.Co</b>                      |
| Location       | Osan-Si, KR                           |
| Contact        | Chon Yeong-Bin                        |
| 510(k) history | 4 submissions · 4 cleared · 2018-2025 |

**REGULATORY CONSULTANT**

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|-----------------|-----------------------------------------------------|
| Consulting firm | <b>Global Medical Standard Consulting Co., Ltd.</b> |
| Contact         | Jong-Hyun Kim                                       |

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/k232047/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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