

**K233777 PRIMED Sterilization Wrap (P100, P200, P300, P400, P500, P600)**May 24, 2024  
182 days to decisionK233777 · Product code: **FRG** · General Hospital  
Source: <https://www.510kdatabase.net/k233777/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Wrap, Sterilization (FRG)          |
| Date received         | Nov 24, 2023                       |
| Decision date         | May 24, 2024                       |
| Days to decision      | 182 days                           |
| Third-party review    | No                                 |
| Combination product   | No                                 |
| PCCP authorized       | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Primed Medical Products, Inc.</b>  |
| Location       | Edmonton, Alberta, CA                 |
| Contact        | Mitra Fard                            |
| 510(k) history | 8 submissions · 8 cleared · 2008-2025 |

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k233777/>. Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 13, 2026