

**K241123 Perpak™ Sterilization Tyvek Pouch**Sep 18, 2024  
148 days to decisionK241123 · Product code: **FRG** · General Hospital  
Source: <https://www.510kdatabase.net/k241123/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wrap, Sterilization (FRG)
Date received	Apr 23, 2024
Decision date	Sep 18, 2024
Days to decision	148 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Km Corp.</b>
Location	Gangwon-Do, KR
Contact	Shin Byung Soon
510(k) history	1 submissions · 1 cleared · 2024-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k241123/> 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 14, 2026