

**K223025 Tyvek Roll with CI for STERLINK Sterilizer**May 9, 2023  
222 days to decisionK223025 · Product code: **FRG** · General Hospital  
Source: <https://www.510kdatabase.net/k223025/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wrap, Sterilization (FRG)
Date received	Sep 29, 2022
Decision date	May 9, 2023
Days to decision	222 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Plasmapp Co.,, Ltd.</b>
Location	Daejeon, KR
Contact	Byeong Geon Song
510(k) history	8 submissions · 8 cleared · 2021-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k223025/> 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 26, 2026