

K212198 Tyvek(R) Roll with CI for STERLINK™ SterilizerOct 22, 2021
100 days to decisionK212198 · Product code: **FRG** · General Hospital
Source: <https://www.510kdatabase.net/k212198/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wrap, Sterilization (FRG)
Date received	Jul 14, 2021
Decision date	Oct 22, 2021
Days to decision	100 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Plasmapp Co.,, Ltd.
Location	Daejeon, KR
Contact	Lee Seung Hun
510(k) history	8 submissions · 8 cleared · 2021-2023

REGULATORY CONSULTANT

Consulting firm	CardioMed Device Consultants, LLC
Contact	Candace Cederman

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

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