

K212338 SterileRight sterilization pouch and rollNov 1, 2021
97 days to decisionK212338 · Product code: **FRG** · General Hospital
Source: <https://www.510kdatabase.net/k212338/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wrap, Sterilization (FRG)
Date received	Jul 27, 2021
Decision date	Nov 1, 2021
Days to decision	97 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Sterileright Packaging Mfg., Inc.
Location	Keelung City, TW
Contact	Thomas Chou
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Sen MU Technology Co., Ltd.
Contact	Uta Shih

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k212338/> Data sourced from FDA 510(k) public records (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. - Generated May 26, 2026