

K221379 Striking LT-Blueline Pouches with TyvekJan 4, 2023
237 days to decisionK221379 · Product code: **FRG** · General Hospital
Source: <https://www.510kdatabase.net/k221379/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wrap, Sterilization (FRG)
Date received	May 12, 2022
Decision date	Jan 4, 2023
Days to decision	237 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Wipak OY
Location	Nastola, FI
Contact	Hanna Marttila
510(k) history	7 submissions · 7 cleared · 2022-2024

REGULATORY CONSULTANT

Consulting firm	Compliance Systems International
Contact	Amanda Singleton

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/k221379/> 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