

K231996 Steriking® LT-Blueline Pouches with Tyvek®Sep 7, 2023
64 days to decisionK231996 · Product code: **FRG** · General Hospital
Source: <https://www.510kdatabase.net/k231996/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Wrap, Sterilization (FRG)
Date received	Jul 5, 2023
Decision date	Sep 7, 2023
Days to decision	64 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k231996/> 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