

K221016 Striking Packaging for Medical DevicesMay 5, 2022
30 days to decisionK221016 · Product code: **FRG** · General Hospital
Source: <https://www.510kdatabase.net/k221016/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Wrap, Sterilization (FRG)
Date received	Apr 5, 2022
Decision date	May 5, 2022
Days to decision	30 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, LLC
Contact	Steven T 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/k221016/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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