

K250321 GCI Sterilization WrappersJun 6, 2025
122 days to decisionK250321 · Product code: **FRG** · General Hospital
Source: <https://www.510kdatabase.net/k250321/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wrap, Sterilization (FRG)
Date received	Feb 4, 2025
Decision date	Jun 6, 2025
Days to decision	122 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	George Courey, Inc.
Location	Laval, CA
Contact	Naab Cort
510(k) history	2 submissions · 2 cleared · 2024-2025

REGULATORY CONSULTANT

Consulting firm	Emergo by UL
Contact	Sarah Fitzgerald

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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