

K251347 Sterilization Pouch/RollJan 28, 2026
273 days to decisionK251347 · Product code: **FRG** · General Hospital
Source: <https://www.510kdatabase.net/k251347/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wrap, Sterilization (FRG)
Date received	Apr 30, 2025
Decision date	Jan 28, 2026
Days to decision	273 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Sterivic Medical Co., Ltd.
Location	Chizhou, CN
Contact	Wanggen Jiang
510(k) history	1 submissions · 1 cleared · 2026-2026

REGULATORY CONSULTANT

Consulting firm	Shanghai SUNGO Management Consulting Co., Ltd.
Contact	Ivy Wang

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