

K241214 ProPel SG3™ Surgical GownSep 10, 2024
133 days to decisionK241214 · Product code: FYA · General Hospital
Source: <https://www.510kdatabase.net/k241214/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Surgical (FYA)
Date received	Apr 30, 2024
Decision date	Sep 10, 2024
Days to decision	133 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Standard Textile Co., Inc.
Location	Cincinnati, OH, US
Contact	Richard Holbert
Website	http://www.standardtextile.com
510(k) history	23 submissions · 23 cleared · 1986-2024

REGULATORY CONSULTANT

Consulting firm	RQM+
Contact	Catherine Kang

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)**510k Database** - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k241214/> 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 13, 2026