

K242844 Medline Level 4 Surgical Gown with Breathable SleevesFeb 26, 2025
159 days to decisionK242844 · Product code: **FYA** · General Hospital
Source: <https://www.510kdatabase.net/k242844/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Surgical (FYA)
Date received	Sep 20, 2024
Decision date	Feb 26, 2025
Days to decision	159 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Medline Industries, LP
Location	Nortfield, IL, US
Contact	Kelsey Closen
Website	https://www.medline.com
510(k) history	29 submissions · 29 cleared · 2022-2026

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