

K253243 Cardinal Health™ Poly Reinforced Surgical GownApr 28, 2026
211 days to decision

K253243 · Product code: FYA · General Hospital

Source: <https://www.510kdatabase.net/k253243/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Gown, Surgical (FYA)
Date received	Sep 29, 2025
Decision date	Apr 28, 2026
Days to decision	211 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Cardinal Health 200, LLC
Location	Waukegan, IL, US
Contact	Brenda Gerena
Website	https://www.cardinalhealth.com
510(k) history	1 submissions · 1 cleared · 2026-2026

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