

K232849 Halyard Tri-Layer AAMI 3 Isolation Gown, L, Blue (54310), Halyard Tri-Layer AAMI 3 Isolation Gown, X-Large, Blue (54311)May 16, 2024
245 days to decisionK232849 · Product code: **FYC** · General Hospital
Source: <https://www.510kdatabase.net/k232849/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Gown, Isolation, Surgical (FYC)
Date received	Sep 14, 2023
Decision date	May 16, 2024
Days to decision	245 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Owens & Minor (O&M) Halyard, Inc.
Location	Mechanicsville, VA, US
Contact	Gabriel Dockery
510(k) history	12 submissions · 12 cleared · 2019-2025

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