

K220333 Medline Orbis LVL 3 Surgical GownMay 18, 2022
103 days to decisionK220333 · Product code: **FYA** · General HospitalSource: <https://www.510kdatabase.net/k220333/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Surgical (FYA)
Date received	Feb 4, 2022
Decision date	May 18, 2022
Days to decision	103 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

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

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