

K182172 Medline Level 4 Surgical Gown (Sirus), Medline Level 4 Surgical Gown (Eclipse), Medline Level 4 Surgical Gown (Aurora)Apr 24, 2019
257 days to decisionK182172 · Product code: **FYA** · General Hospital
Source: <https://www.510kdatabase.net/k182172/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Surgical (FYA)
Date received	Aug 10, 2018
Decision date	Apr 24, 2019
Days to decision	257 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Medline Industries, Inc.
Location	Mchenry, IL, US
Contact	Pauline Maralit
510(k) history	238 submissions · 234 cleared · 1977-2024

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