

K190950 Medline Level 2 Surgical Gown (Eclipse Non-Reinforced), Medline Level 3 Surgical Gown (Eclipse Fabric Reinforced), Medline Level 3 Surgical Gown (Sirus Non-Reinforced), Medline Level 3 Surgical Gown (Sirus Fabric Reinforced), Medline Level 3 Surgical Gown (Aurora Non Reinforced & Aurora Fabric Reinforced)Jul 4, 2019
84 days to decisionK190950 · Product code: FYA · General Hospital
Source: <https://www.510kdatabase.net/k190950/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Surgical (FYA)
Date received	Apr 11, 2019
Decision date	Jul 4, 2019
Days to decision	84 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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