

**K203237 Dukal Sterile AAMI Level 3 Reinforced Surgical Gown, Sterile AAMI Level 3 Surgical Gown, Sterile AAMI Level 4 Surgical Gown, and Sterile AAMI Level 4 Splicing Surgical Gown**

Mar 18, 2022  
500 days to decision

K203237 · Product code: FYA · General Hospital  
Source: <https://www.510kdatabase.net/k203237/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Surgical (FYA)
Date received	Nov 3, 2020
Decision date	Mar 18, 2022
Days to decision	500 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Dukal Corporation</b>
Location	Hauppauge, NY, US
Contact	Megan Quevedo
510(k) history	7 submissions · 7 cleared · 2007-2022

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k203237/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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