

**K212464 Dukal Corporation AAMI Level 4 Open-Back Protective Gown**Mar 30, 2022  
236 days to decisionK212464 · Product code: **QPC** · General Hospital  
Source: <https://www.510kdatabase.net/k212464/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Non-sterile, Non-isolation, Intended To Provide Moderate Or High Barrier Protection (QPC)
Date received	Aug 6, 2021
Decision date	Mar 30, 2022
Days to decision	236 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/k212464/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](https://accessdata.fda.gov). - Generated May 26, 2026