

**K242689 AAMI Level 4 Protective**Jan 13, 2025  
129 days to decisionK242689 · Product code: **QPC** · General Hospital  
Source: <https://www.510kdatabase.net/k242689/>**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	Sep 6, 2024
Decision date	Jan 13, 2025
Days to decision	129 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement
Other names	Gown

**APPLICANT**

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Company	<b>Azac Group</b>
Location	City Of Industry, CA, US
Contact	Yen Ping Shan
510(k) history	2 submissions · 2 cleared · 2021-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>Qpm Consulting</b>
Contact	Robert Seiple

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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**510k Database** - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k242689/> 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 14, 2026