

**K212717 Paneffort AAMI Level 3 Isolation Gown**Nov 30, 2022  
460 days to decisionK212717 · Product code: **FYC** · General Hospital  
Source: <https://www.510kdatabase.net/k212717/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Isolation, Surgical (FYC)
Date received	Aug 27, 2021
Decision date	Nov 30, 2022
Days to decision	460 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Paneffort, LLC</b>
Location	Rochester,, NY, US
Contact	Harry Harry
510(k) history	2 submissions · 2 cleared · 2022-2022

**REGULATORY CONSULTANT**

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Consulting firm	<b>Freyr Solutions</b>
Contact	Shilpa Gampa

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k212717/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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