FDA 510(k) Premarket Notification

K212717 Paneffort AAMI Level 3 Isolation Gown

CLEARED

Nov 30, 2022
460 days to decision

K212717 · Product code: **FYC** · General Hospital
Source: https://www.510kdatabase.net/k212717/

SUBMISSION DETAILS

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

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

REGULATORY CONSULTANT

Consulting firm	**Freyr Solutions**
Contact	Shilpa Gampa

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