

K221409 Paneffort 3-ply Surgical and Procedural MasksJul 25, 2022
70 days to decisionK221409 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k221409/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	May 16, 2022
Decision date	Jul 25, 2022
Days to decision	70 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Paneffort, LLC
Location	Rochester,, NY, US
Contact	Harry No Last Name Provided
510(k) history	2 submissions · 2 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	Freyr Solutions
Contact	Vardhini Kirthivas

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

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