

**K222426 Perfetta Moderate Medical Face Mask**Sep 2, 2022  
22 days to decisionK222426 · Product code: **FXX** · General Hospital  
Source: <https://www.510kdatabase.net/k222426/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Aug 11, 2022
Decision date	Sep 2, 2022
Days to decision	22 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Phu Bao Group Company Limited</b>
Location	Ho Chi Minh, VN
Contact	Le Pham Minh Ngoc
510(k) history	1 submissions · 1 cleared · 2022-2022

**REGULATORY CONSULTANT**

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Consulting firm	<b>Regulatory Technology Services, LLC</b>
Contact	Prithul Bom

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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