

**K253060 Sterile Latex Powder Free Surgical Gloves**May 22, 2026  
242 days to decisionK253060 · Product code: **KGO** · General Hospital  
Source: <https://www.510kdatabase.net/k253060/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Surgeon&apos;s Gloves (KGO)
Date received	Sep 22, 2025
Decision date	May 22, 2026
Days to decision	242 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Protect Gloves Company Limited</b>
Location	Rayong, TH
Contact	Nathaphon Wachakorn
510(k) history	1 submissions · 1 cleared · 2026-2026

**REGULATORY CONSULTANT**

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Consulting firm	<b>Shanghai SUNGO Management Consulting Co., Ltd.</b>
Contact	Kiwi Xu

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/k253060/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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