

**K230573 Powder Free Latex Patient Examination Glove, Black Colored, Non-sterile, with Protein Content labeling Claim (Contains 50 ug per dm2 of glove or less of Total Water Extractable Protein)**Jun 13, 2023  
104 days to decisionK230573 · Product code: LYY · General Hospital  
Source: <https://www.510kdatabase.net/k230573/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	Mar 1, 2023
Decision date	Jun 13, 2023
Days to decision	104 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Kossan International Sdn Bhd</b>
Location	Klang, MY
Contact	Cho Sow Fong
510(k) history	12 submissions · 12 cleared · 2015-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k230573/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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