

**K211601 Powder Free Latex Examination Glove, Non-Sterile**Aug 22, 2022  
455 days to decisionK211601 · Product code: LYY · General Hospital  
Source: <https://www.510kdatabase.net/k211601/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	May 24, 2021
Decision date	Aug 22, 2022
Days to decision	455 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Wrp Asia Pacific Sdn. Bhd.</b>
Location	Salak Tinggi, Sepang Selangor, MY
Contact	Siti Syamimie Atirah Binti Mat
510(k) history	46 submissions · 46 cleared · 1999-2024

**REGULATORY CONSULTANT**

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Consulting firm	<b>Sg Global, LLC</b>
Contact	Saravanan Ramasamy

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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