

K213509 Latex Examination Gloves, Powder FreeApr 8, 2022
157 days to decisionK213509 · Product code: LYY · General Hospital
Source: <https://www.510kdatabase.net/k213509/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	Nov 2, 2021
Decision date	Apr 8, 2022
Days to decision	157 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Shandong Intco Medical Products Co, Ltd.
Location	Qingzhou, CN
Contact	Haisheng Yu
510(k) history	4 submissions · 4 cleared · 2022-2023

REGULATORY CONSULTANT

Consulting firm	Intco Medical Industries, Inc.
Contact	John Zhao

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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