

K212309 Non-sterile, Powder-Free Latex Examination GloveApr 8, 2022
259 days to decisionK212309 · Product code: LYY · General Hospital
Source: <https://www.510kdatabase.net/k212309/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Latex Patient Examination Glove (LYY)
Date received	Jul 23, 2021
Decision date	Apr 8, 2022
Days to decision	259 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Sri Trang Gloves (Thailand) Public Company Limited
Location	Hatyai, TH
Contact	Jarinya Jirojkul
510(k) history	8 submissions · 8 cleared · 2020-2024

REGULATORY CONSULTANT

Consulting firm	Sri Trang USA, Inc.
Contact	M. Jordan Smith

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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