

K250069 Powder Free Natural Rubber Latex Examination Gloves – Blue, Non-Sterile and Protein Claim Of 50 Micrograms per dm2 Or Less Protein

Apr 29, 2025
109 days to decisionK250069 · Product code: LYY · General Hospital
Source: <https://www.510kdatabase.net/k250069/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	Jan 10, 2025
Decision date	Apr 29, 2025
Days to decision	109 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Comfort Rubber Gloves Industries Sdn. Bhd.
Location	Matang, MY
Contact	Sumathi Saravana Sami
Website	http://www.comfort-rubber.com.my/
510(k) history	15 submissions · 15 cleared · 1994-2025

Comfort Rubber Gloves Industries Sdn. Bhd. manufactures examination gloves for healthcare settings. The company operates with a manufacturing facility in Matang, Malaysia. The company has received FDA 510(k) clearances from total submissions since 1994. All submissions focus on General Hospital devices. The latest clearance was granted in 2025, confirming active regulatory engagement. Product specialization centers on powder-free examination gloves in multiple materials and colors. Recent cleared devices include nitrile and natural rubber latex formulations. Many products...
