

K974424 COMFORT RUBBER GLOVES INDUSTRIES SDN BHDApr 23, 1998
150 days to decisionK974424 · Product code: LYY · General Hospital
Source: <https://www.510kdatabase.net/k974424/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	Nov 24, 1997
Decision date	Apr 23, 1998
Days to decision	150 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Comfort Rubber Gloves Industries Sdn. Bhd.
Location	Matang, MY
Contact	CHEE YONG FOO
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...
