

K002065 PATIENT LATEX POLYMER COATED POWDER-FREE GLOVES, CONTAINS 50 MICROGRAM OR LESS OF TOTAL WATER EXTRACTABLE PROTEIN PER GRAug 22, 2000
46 days to decisionK002065 · Product code: LYY · General Hospital
Source: <https://www.510kdatabase.net/k002065/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	Jul 7, 2000
Decision date	Aug 22, 2000
Days to decision	46 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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