

**K943044 ROYAL SHIELD NON-STERILE LATEX EXAM GLOVES-
STRAWBERRY**

Sep 26, 1994
91 days to decision

K943044 · Product code: LYY · General Hospital
Source: <https://www.510kdatabase.net/k943044/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	Jun 27, 1994
Decision date	Sep 26, 1994
Days to decision	91 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Shield Gloves Manufacturer (M) Sdn Bhd
Location	Petaling Jaya, MY
Contact	KATHERINE OOI
510(k) history	18 submissions · 18 cleared · 1994-2001

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k943044/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated July 4, 2026