

**K953496 ROYAL SHIELD NON-STERILE POWDER-FREE
HYPOALLERGENIC LATEX EXAMINATION GLOVES**Sep 8, 1995
44 days to decisionK953496 · Product code: LYY · General Hospital
Source: <https://www.510kdatabase.net/k953496/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	Jul 26, 1995
Decision date	Sep 8, 1995
Days to decision	44 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k953496/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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