

K945031 ROYALSHIELD NON-STERILE POWDER-FREEJan 11, 1995
90 days to decision

K945031 · Product code: LYY · General Hospital

Source: <https://www.510kdatabase.net/k945031/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	Oct 13, 1994
Decision date	Jan 11, 1995
Days to decision	90 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

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