

K951455 SCIPOTEX (PINK)Apr 28, 1995
30 days to decisionK951455 · Product code: LYY · General Hospital
Source: <https://www.510kdatabase.net/k951455/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	Mar 29, 1995
Decision date	Apr 28, 1995
Days to decision	30 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Wembley Rubber Products (M) Sdn Bhd
Location	Kuala Lumpur, Malaysia, MY
Contact	ONG G CHEE
510(k) history	61 submissions · 61 cleared · 1990-1999

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k951455/> 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 May 26, 2026