

K934133 PATIENT EXAMINATION GLOVES (POWDER FREE GLOVES)Jan 7, 1994
142 days to decisionK934133 · Product code: LYY · General Hospital
Source: <https://www.510kdatabase.net/k934133/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	Aug 18, 1993
Decision date	Jan 7, 1994
Days to decision	142 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Supergrade Healthcare Products Sdn. Bhd.
Location	Penang, MY
Contact	OOI BOON SENG
510(k) history	3 submissions · 3 cleared · 1989-2002

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k934133/> 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 3, 2026