

**K042805 POWDER FREE NITRILE PATIENT EXAMINATION
GLOVES, BLUE COLORED NON-STERILE**Dec 16, 2004
65 days to decisionK042805 · Product code: **LZC** · General Hospital
Source: <https://www.510kdatabase.net/k042805/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Medical Glove, Specialty (LZC)
Date received	Oct 12, 2004
Decision date	Dec 16, 2004
Days to decision	65 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Perusahaan Getah Asas Sdn. Bhd.
Location	42000 Port Kelang, S.D.E., MY
Contact	KK LEONG
510(k) history	30 submissions · 30 cleared · 1989-2010

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k042805/> 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 June 20, 2026