

K971665 SMART - FIT, POWDERFREE NITRILE EXAMINATION GLOVESJun 27, 1997
52 days to decisionK971665 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k971665/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	May 6, 1997
Decision date	Jun 27, 1997
Days to decision	52 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Sj Medical Products (M) Sdn Bhd
Location	Klang, Selangor, MY
Contact	FOO KHON PU
510(k) history	5 submissions · 5 cleared · 1994-1997

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k971665/> 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 6, 2026