

**K003985 POWDERFREE NITRILE PATIENT EXMINATION
GLOVE**Feb 9, 2001
45 days to decisionK003985 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k003985/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Dec 26, 2000
Decision date	Feb 9, 2001
Days to decision	45 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Guthrie Medicare Products (Melaka) Sdn Bhd
Location	Kelemak, Alor Gajah, Melaka, MY
Contact	SUSAN D GOLDSTEIN-FALK
510(k) history	12 submissions · 12 cleared · 1991-2001

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k003985/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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