

K003922 NITRILE EXAMINATION GLOVES (POWERED)Feb 15, 2001
57 days to decisionK003922 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k003922/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Dec 20, 2000
Decision date	Feb 15, 2001
Days to decision	57 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

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