

K010078 GUTHRIE SHIELD PLUS BLUE LATEX EXAMINATION GLOVES (POWDER-FREE)

Jan 29, 2001
19 days to decision

K010078 · Product code: LYY · General Hospital
Source: <https://www.510kdatabase.net/k010078/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	Jan 10, 2001
Decision date	Jan 29, 2001
Days to decision	19 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.net

Device record: <https://www.510kdatabase.net/k010078/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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