

K972177 POWDERED NITRILE EXAMINATION GLOVE, BLUE OR WHITE (NON-COLORED)

Jul 29, 1997
49 days to decision

K972177 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k972177/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Jun 10, 1997
Decision date	Jul 29, 1997
Days to decision	49 days
Third-party review	Yes
Summary / Statement	Statement

APPLICANT

Company	Absolute Synthetic Technologies Malaysia Sdn. Bhd.
Location	Kamunting, Taiping, Perak, MY
Contact	WOLFE BIRKIE
510(k) history	3 submissions · 3 cleared · 1997-1997

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k972177/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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