

K061553 NON-STERILE, POWDER-FREE BLACK NITRILE EXAMINATION GLOVES

Jul 17, 2006
42 days to decision

K061553 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k061553/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Jun 5, 2006
Decision date	Jul 17, 2006
Days to decision	42 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Yty Industry (Manjung) Sdn Bhd
Location	Selangor, Malaysia, MY
Contact	JANNA P TUCKER
510(k) history	27 submissions · 27 cleared · 1989-2023

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Device record: <https://www.510kdatabase.net/k061553/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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