

K031384 MULTIPLE PRIVATE LABELED, NON-STERILE, POWDER-FREE, POLYURETHANE WHITE COLOR, EXAMINATION GLOVES (INTACTA POLYURETHANE G

Jun 17, 2003
47 days to decision

K031384 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k031384/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	May 1, 2003
Decision date	Jun 17, 2003
Days to decision	47 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/k031384/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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