

K220644 Non-sterile, Powder Free, ambidextrous, textured, beaded cuff, single use, Doffy® Nitrile Examination Glove, Tested for use with Chemotherapy DrugsMar 25, 2023
386 days to decisionK220644 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k220644/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Mar 4, 2022
Decision date	Mar 25, 2023
Days to decision	386 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

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

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