

K160467 Sterile Powder Free Nitrile Examination Gloves, Blue Colored. Tested For Use with Chemotherapy Drugs, with Non-Pyrogenic Labeling Claim

Aug 2, 2016
165 days to decision

K160467 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k160467/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Feb 19, 2016
Decision date	Aug 2, 2016
Days to decision	165 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Kossan International Sdn Bhd
Location	Klang, MY
Contact	Cho Sow Fong
510(k) history	12 submissions · 12 cleared · 2015-2026

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k160467/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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