

K191800 Sterile Powder Free Nitrile Examination Glove, Blue Colored, with Non-Pyrogenic Labeling Claim, Sterile Powder Free Nitrile Examination Glove, White Colored, with Non-Pyrogenic Labeling Claim

Sep 16, 2019
75 days to decision

K191800 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k191800/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Jul 3, 2019
Decision date	Sep 16, 2019
Days to decision	75 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
