

K211810 Shamrock Powder Free Blue Nitrile Examination Gloves (Tested for use with Chemotherapy Drugs and Fentanyl)May 23, 2022
346 days to decisionK211810 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k211810/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Jun 11, 2021
Decision date	May 23, 2022
Days to decision	346 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Pt. Shamrock Manufacturing Corpora
Location	Kab. Deli Serdang, ID
Contact	Jeni Chuason
510(k) history	1 submissions · 1 cleared · 2022-2022

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