

**K213144 Biodegradable Powder Free Vinyl Examination Gloves
Blue, Green and White Colors**Dec 22, 2021
86 days to decisionK213144 · Product code: LYZ · General Hospital
Source: <https://www.510kdatabase.net/k213144/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Vinyl Patient Examination Glove (LYZ)
Date received	Sep 27, 2021
Decision date	Dec 22, 2021
Days to decision	86 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Shen Wei (Usa), Inc.
Location	Foster City, CA, US
Contact	Cheryl Reep
510(k) history	58 submissions · 58 cleared · 1989-2022

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