

**K211620 Biodegradable Powder Free Latex Examination Gloves
Natural, Blue, Black and Green Colors with protein content
labeling claim (50 micrograms or less)**Aug 19, 2021
85 days to decisionK211620 · Product code: LYY · General Hospital
Source: <https://www.510kdatabase.net/k211620/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	May 26, 2021
Decision date	Aug 19, 2021
Days to decision	85 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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