

K202082 Biodegradable Powder Free Nitrile Examination Glove, Green-White and Orange-White Colors with Low Dermatitis Potential Claim and Tested for Use with Chemotherapy Drugs, Fentanyl Citrate and Simulated Gastric Acid

Mar 17, 2021
233 days to decision

K202082 · Product code: **LZA** · General Hospital

Source: <https://www.510kdatabase.net/k202082/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Jul 27, 2020
Decision date	Mar 17, 2021
Days to decision	233 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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k202082/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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