

K202078 Biodegradable Thermoplastic Elastomer Examination (TPE) GloveMar 5, 2021
221 days to decisionK202078 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k202078/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Jul 27, 2020
Decision date	Mar 5, 2021
Days to decision	221 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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