

**K172678 THERMOPLASTIC ELASTOMER EXAMINATION (TPE)
GLOVE**Nov 24, 2017
80 days to decisionK172678 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k172678/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Sep 5, 2017
Decision date	Nov 24, 2017
Days to decision	80 days
Third-party review	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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