

K162312 Biodegradable Powder Free Nitrile Exam Gloves with Aloe Vera, Green Color

Jul 25, 2017
341 days to decision

K162312 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k162312/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Aug 18, 2016
Decision date	Jul 25, 2017
Days to decision	341 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k162312/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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