

K192111 Biodegradable Nitrile Examination Powder Free Glove, GreenSep 3, 2020
395 days to decisionK192111 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k192111/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Aug 5, 2019
Decision date	Sep 3, 2020
Days to decision	395 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Top Glove Sdn. Bhd.
Location	Malaysia, ML
Contact	Noor Akilah Saidin
510(k) history	17 submissions · 17 cleared · 1991-2020

REGULATORY CONSULTANT

Consulting firm	Tg Medical (Usa), Inc.
Contact	David Lim

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k192111/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 29, 2026