

**K193121 GEN 2 Nitrile Examination Glove (Blue) With Low Dermatitis Potential Claim and with tested for use with Chemotherapy Drugs Claims**

Mar 20, 2020  
129 days to decision

K193121 · Product code: **LZA** · General Hospital  
Source: <https://www.510kdatabase.net/k193121/>

**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Nov 12, 2019
Decision date	Mar 20, 2020
Days to decision	129 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Eco Medi Glove Sdn. Bhd.</b>
Location	Kamunting Perak, MY
Contact	Suresh Kumar
510(k) history	15 submissions · 15 cleared · 2014-2024

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k193121/> 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 May 26, 2026