

**K203593 Patient Examination Gloves**Mar 19, 2021  
100 days to decisionK203593 · Product code: **LZA** · General Hospital  
Source: <https://www.510kdatabase.net/k203593/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Dec 9, 2020
Decision date	Mar 19, 2021
Days to decision	100 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Guangdong Kingfa Sci. &amp; Tech.Co., Ltd.</b>
Location	Qingyuan, CN
Contact	Xiaoge Yu
510(k) history	14 submissions · 14 cleared · 2020-2024

**REGULATORY CONSULTANT**

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Consulting firm	<b>Landlink Healthcare Technology (Shanghai) Co., Ltd.</b>
Contact	Shelley Li

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.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k203593/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 25, 2026