

K183068 Nitrile Glove Powder Free WhiteDec 21, 2018
46 days to decisionK183068 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k183068/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Nov 5, 2018
Decision date	Dec 21, 2018
Days to decision	46 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Haining Medical Products Co., Ltd.
Location	Tangshan, CN
Contact	Zhiming Yao
510(k) history	3 submissions · 3 cleared · 2016-2018

REGULATORY CONSULTANT

Consulting firm	Shanghai Truthful Information Technology Co., Ltd.
Contact	Boyle Wang

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k183068/> 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