

K182528 Nitrile Glove Powder Free BlackNov 15, 2018
62 days to decisionK182528 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k182528/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Sep 14, 2018
Decision date	Nov 15, 2018
Days to decision	62 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](https://accessdata.fda.gov)

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