

K211012 Nitrile Patient Examination GlovesJul 23, 2021
109 days to decisionK211012 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k211012/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Apr 5, 2021
Decision date	Jul 23, 2021
Days to decision	109 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Huayuan Medical Technology(Shangqiu) Co., Ltd.
Location	Shangqiu, CN
Contact	Huamei Wang
510(k) history	3 submissions · 3 cleared · 2021-2021

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

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