

K211714 Nitrile Exam Gloves, Powder Free,Blue (Tested for Use with Chemotherapy)Aug 4, 2021
62 days to decisionK211714 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k211714/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Jun 3, 2021
Decision date	Aug 4, 2021
Days to decision	62 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Hengchang (Dongying) Medical Technology Co., Ltd.
Location	Dongying, CN
Contact	Li Jing
510(k) history	2 submissions · 2 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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