

K213040 Nitrile Patient Examination Gloves Blue Tested For Use With Chemotherapy Drugs, Nitrile Patient Examination Gloves Blue Violet Tested For Use With Chemotherapy Drugs, Nitrile Patient Examination Gloves Black Tested For Use With Chemotherapy Drugs

Apr 27, 2022
217 days to decision

K213040 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k213040/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Sep 22, 2021
Decision date	Apr 27, 2022
Days to decision	217 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k213040/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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